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IN THE

Supreme Court of the United States

OCTOBER TERM, 1942

No. 424

FEDERAL SECURITY ADMINISTRATOR,
Petitioner,

vs.

THE QUAKER OATS COMPANY,
Respondent.

On Writ of Certiorari to the United States Circuit Court of Appeals for the Seventh Circuit.

BRIEF FOR RESPONDENT.

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BRIEF FOR RESPONDENT.

INTRODUCTION.

This case arises under the Federal Food, Drug and Cosmetic Act of 1938. It is the first attempt by the government to make it a criminal offense to market a long established, widely used, *nutritionally superior* product, while permitting the sale of an *admittedly comparatively inferior* one.

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[1] Following the practice of petitioner's brief, we refer to him as the "Administrator" rather than as the "petitioner." Italics in this brief are supplied unless otherwise noted.

The *superior* product is farina with Vitamin D. The *relatively inferior* one is farina without Vitamin D. The case presents no element or suggestion whatsoever of adulteration, dilution, substitution, mislabeling, imitation, fraud, misrepresentation or deception. The extraordinary issue is presented of whether the Administrator may, through the device of establishing definitions and standards of identity under Section 401 of the Food, Drug and Cosmetic Act (21 U. S. C. A. 341), prevent respondent, a manufacturer of farina, from continuing a practice carried on by it for over 10 years of improving this food by the addition to it of nutritionally beneficial amounts of Vitamin D—an element which the Administrator, upon the evidence, found was widely deficient in the diet of infants and children.

Respondent has for over ten years manufactured and sold farina with Vitamin D added (R. 218). Millions of packages of respondent's products are sold yearly and by reason of its economy, the product is "widely available" and "known country wide" (R. 218). Farina is used largely as a breakfast food and as an ingredient of macaroni products (R. 207, 213; Finding 81, R. 626). It is extensively used as a cereal food for children, and in many cases is the only cereal food used during a period of their growth (R. 217, 272, 626). Respondent has been adding Vitamin D in carefully regulated amounts to its farina since April, 1932 (R. 218). Its product is labeled "Quaker Farina Wheat Cereal enriched with Vitamin D," or in some instances, "Quaker Farina enriched by the Sunshine Vitamin" and the mode of Vitamin D fortification or improvement of the product is described on the label (R. 218, 640).

Vitamin D is that vitamin which functions in regulating the metabolism of calcium and phosphorus in the body and is, therefore, concerned with the proper formation of bones

and teeth (R. 78). About 99% of the calcium in the body is contained in its skeleton (R. 78-9). Bones are living things like all other tissues of the body and there is a constant interchange of mineral salts contained therein (R. 85). Vitamin D facilitates the absorption of calcium and phosphorus from the alimentary tract (R. 78). The principal need for Vitamin D is in the infant and growing child—both large consumers of farina—in the prevention and cure of rickets and the building of strong bones and teeth (R. 80, 317-18, 361, 368-9). In the adult, deficiency of Vitamin D causes osteoporosis and perhaps certain other manifestations of improper calcium and phosphorus assimilation (R. 84-6).

Vitamin D, of all the known vitamins, is the one preeminently and notoriously deficient in the normal diet (R. 78-80, 82-4, 423). It is "the scarcest of the known vitamins" (R. 423). It is contained in substantial quantities in cod liver oil and in very small quantities in certain foods such as the yolks of eggs, milk and other dairy products (R. 79-80). It would take eight to twelve eggs per day to furnish an individual with a good supply of Vitamin D (R. 79). It would take 254 servings of white bread to supply the consumer with the Vitamin D equivalent of one-half a teaspoon of cod liver oil.

Sunlight as a source of Vitamin D is inadequate (R. 80, 423-33; Wisconsin Foundation Exs. S—BB, R. 529-53). Clouds, dust and smoke in the air act as screens to filter out the effective ultra violet rays from the sun just as does ordinary window glass (R. 425, Wisconsin Foundation Ex. T, R. 542). Studies on the number of tons of dust deposited per square mile during a year period show all the way from 349 tons per square mile to 1876 tons per square mile (R. 429-30, Wisconsin Foundation Ex. AA, R. 551). The number of clear days during the year when any sunshine at all is available is remarkably small (R. 426, Wisconsin Foundation Ex. V, R. 544-5).

Further, the sun's rays are effective in producing a Vitamin D effect only during certain short seasons of the year—particularly the summer months—and only during certain periods of the day—around noon when the sun is high (R. 426-7, Wisconsin Foundation Ex. W, R. 547). The clothing worn by civilized people today also prevents the sun's rays from being effective in producing any Vitamin D effect (R. 430-31). The ineffectiveness of sunlight and the widespread deficiency of Vitamin D are shown by a clinical study on the prevalence of rickets in the cities of Portland, Oregon, and San Diego, California (R. 428-9). The study, covering 1,000 children, showed that 95% of those in Portland and 73% of those in San Diego showed signs of rickets (R. 429).

The Court below summarized this evidence as follows (R. 682-3):

> "Vitamin D functions in regulating the metabolism of calcium and phosphorus in the body and is, therefore, concerned with the proper formation of bones and teeth. It is recognized as especially beneficial in the infant and growing child as a preventative and therapy of rickets and the building of strong bones and teeth. It is also an essential vitamin for adults. There is medical testimony to the effect that of all the known vitamins, it is the one most deficient in normal diet and should, therefore, be supplied in foods which are consumed regularly by the great mass of population, particularly those in the low income groups. While the Administrator found that milk was the most appropriate carrier for vitamin D, it is not disputed but that farina is also a proper carrier. Vitamin D in nature is found almost exclusively in sunshine and certain fish livers which are unavailable to humans in the normal diet. Therefore, as we understand, this vitamin is deficient in ordinary food products except when artificially supplied."

The Administrator found as a fact that (R. 617):

> "A deficiency of Vitamin D exists in large numbers of infants and children."

Also, in promulgating regulations regarding the labeling of products represented for special dietary use based upon their vitamin or mineral content under Section 403 (j) of the Act, the Administrator has found as a fact that the minimum daily requirement of Vitamin D for all persons, *irrespective of age*, is 400 U. S. P. units (6 Fed. Reg. 5923, Nov. 22, 1941).[2] This is the amount of Vitamin D supplied by a normal daily one ounce serving of respondent's farina (R. 218).[3]

Clinical tests upon respondent's product have shown excellent results in the improvement of health of children fed (R. 218).

In view of the scarcity of Vitamin D and the need for it in the diet, nutritionists agree that this vitamin should be added to foods which are consumed regularly by the great

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[2] Section 403 (j) of the Act (21 U. S. C. A. 343 (j)) reads:

> "A food shall be deemed to be misbranded—
>
> • • • • •
>
> "(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Administrator determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses."

[3] "81. *The most common dietary deficiency diseases in infants* are scurvy, *rickets*, and nutritional anemia, *caused respectively by deficiencies of* vitamin C, *vitamin D*, and iron in human milk or in preparations used as substitutes for human milk, including, among others, cows' milk and evaporated milk in which the quantities of such substances have not been increased." (Finding of fact made by the Administrator pursuant to hearings under Section 403(j). 6 Fed. Reg. 5924, Nov. 22, 1941).

mass of our population, particularly those in the low income groups (R. 82-3, 182-3, 217-19, 555-6). This is because Vitamin D deficiencies are most widespread among people who (R. 428)

> "* * * cannot afford to buy Vitamin D in the form of antirachitic agents. * * * That is why the supplying of Vitamin D in some commonly consumed food on a communal scale will result in much better nutrition".

The slum baby, who may well receive no solid food except farina during its first few months of life (R. 217), will probably not get Vitamin D in the form of expensive cod liver oil, Viosterol or Vitamin D fortified milks because the poor mother can ill afford such products.

The scientists who testified at the hearing below agreed that farina is a proper and appropriate carrier for Vitamin D (R. 92, 189, 217-19, 555-6).[4] The reasons for this view are:

(1) Farina, by reason of its economy, reaches that group of people most likely to suffer from dietary deficiencies, i.e., the low income groups (R. 82-3, 182-3, 423, 427-8).

(2) Farina is widely consumed by infants and children, the age groups of the population suffering most from Vitamin D deficiencies and, therefore, most needing additional amounts of Vitamin D (Finding 35, R. 617; Finding 81, R. 626; R. 217, 272).

(3) From the physical standpoint, Vitamin D may easily be incorporated in farina, will remain stable therein and

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[4] The Administrator refers to testimony "against permitting the inclusion of Vitamin D in farina" (Adm. Br. 54). All of the testimony there referred to related to flour. Since flour is largely consumed by adul[ts] where the need for additional Vitamin D is nowhere near as great as in infants and children, some opinions were expressed that Vitamin D is not necessary in flour (R. 361, 386, 413, 497). *Not one witness testified specifically against the addition of Vitamin D to farina.*

is not destroyed by the heat of cooking processes (R. 92, 189, 217-9).

Milk and other dairy products contain only very small amounts of Vitamin D (R. 79). Milk, by reason of its calcium and phosphorus content (these minerals are made available in bodily metabolism by Vitamin D), is a good carrier of Vitamin D (Finding 40, R. 618). But in order for a consumer to get substantial quantities of this vitamin from milk, the producer must first go to the expense of putting it there and it is the consumers who need a low cost product who suffer most from Vitamin D deficiency (R. 427-8). The Administrator found that (R. 618):

> "The addition, however, of Vitamin D and calcium as optional ingredients to an enriched flour or enriched self-rising flour, will serve a useful purpose *for the benefit of persons who do not consume sufficient dairy products.*"

By Finding 83, the Administrator found the above quoted finding to be applicable to the "enrichment of farina" (R. 626). In view of the fact that farina, far more than flour, is widely consumed by those most apt to suffer from a Vitamin D deficiency, Finding 40 (R. 618) is even more applicable to farina than to flour.

Less than 6% of the milk sold is Vitamin D fortified (R. 79). Moreover, farina is almost always consumed with milk or cream and from this standpoint is a very desirable vehicle for Vitamin D. Further, one eminent scientist presented evidence that in his opinion the fortification of cereal products with Vitamin D (R. 556) "would probably do as much to make Vitamin D available to the public as fortification of milk with this essential." This opinion is based upon recent work in the chemistry of nutrition showing that most manufactured cereals today contain phosphorus in the form of phytic acid which is not

readiiy available to the human in the absence of Vitamin D (R. 555-6).

Under the Administrator's two standards—for farina and "enriched farina," respectively—respondent cannot lawfully continue the sale of its present product. Respondent has never marketed "enriched farina" or any product under that name, nor does the record show that anyone else has sold such a product. It is a fictitious product invented by the Administrator. It must be labeled "enriched farina" and its label need not disclose its required ingredients—Vitamin B_1, riboflavin, nicotinic acid and iron.

Respondent has sold farina. The Administrator's order prohibits respondent from improving its product by the addition of Vitamin D thereto by making it a criminal offense so to do. It is the farina standard, not the enriched farina standard, that respondent violates—*violates by improving the product*. Thus the Administrator's order prevents respondent from making its contribution to the reduction in the widespread deficiency of Vitamin D which the Administrator found exists "in large numbers of infants and children" (R. 617).

QUESTIONS PRESENTED.

We disagree with the statement of the "Questions Presented" in the Administrator's brief (p. 2). More properly stated the questions presented in this case are:

1. Whether the farina and enriched farina standards, considered either separately or together, are reasonable under Section 401 of the Act.

2. Whether the two standards are supported by substantial evidence in accordance with the requirements of Section 701 (e) of the Act.

3. Whether the two standards will accomplish the purposes of Section 401 of the Act.

In its presentation in the Court below, respondent treated the two standards separately whereas the Administrator attempted to treat them together and thus set off one standard against the other. The Court below agreed with respondent that the standards were properly treated separately (R. 683). However, the result is the same regardless of which treatment is followed, as the Court below pointed out (R. 683).

SUMMARY OF ARGUMENT.

I. The Administrator's Standards Are Invalid Because Unreasonable.

A. A definition and standard of identity to be valid must be reasonable.

The definitions and standards of identity for farina and enriched farina are unreasonable because

B. They impose upon the addition of Vitamin D to farina the unreasonable condition that Vitamin B_1, nicotinic acid, iron and riboflavin also be added thereto.

C. They deprive the consuming public of an established beneficial product and thus deprive infants and children, and particularly those in the low income groups, of much needed Vitamin D heretofore obtained in respondent's farina with Vitamin D. Thus they invade the consumer's fundamental right to good, wholesome food.

D. They increase, rather than diminish, the deficiency of Vitamin D which the Administrator found exists in "large numbers of infants and children in the United States" (R. 617).

E. They destroy an established business in a nutritionally improved and superior product and thus invade respondent's fundamental right to continue its business of

supplying the consuming public with a better food, as the Court below said, "without deception, fraud or misrepresentation of any kind" (R. 683).

F. They exclude Vitamin D from farina while permitting it in enriched farina.

G. They prohibit the nutritional improvement of a food product and thus place a ceiling over quality rather than a floor under it.

H. The Administrator's reasons do not support the two standards because

(1) The standards do not promote honesty and fair dealing in the interest of consumers.

(2) The Administrator's "instinct theory" is fallacious.

(3) The standards are unnecessary to facilitate enforcement.

(4) The difficulty in establishing the standards does not excuse unreasonable ones.

I. They do not conform with the principles and limitations of the Act.

II. The Standards Are Invalid Because Not Based Upon Substantial Evidence of Record.

A. A definition and standard of identity to be valid must be based upon substantial evidence.

B. The exclusion of Vitamin D from the farina standard is not supported by substantial evidence of record. There is no substantial evidence supporting the Administrator's finding of likelihood of consumer confusion. The evidence relied upon by the Administrator is speculative and conjectural. There is no evidence that respondent's practices have ever confused or misled anyone.

C. Respondent's contention that Vitamin D should be included as an optional ingredient in the farina standard is supported by substantial evidence. The Administrator ignored all of the evidence that Vitamin D should be included as an optional ingredient in farina, including evidence of

1. The deficiency of Vitamin D among infants and children, principal consumers of farina.
2. The value of Vitamin D in the diet in building strong bones and teeth and in the prevention and cure of rickets.
3. Opinion evidence of scientists that farina is an appropriate carrier for Vitamin D.
4. Respondent's prior commercial usage of Vitamin D in farina.

III. The Farina and Enriched Farina Standards Do Not Accomplish the Purposes of the Act.

A. The purposes of the Act are to secure the purity of foods and to inform purchasers of what they are buying.

B. The definitions and standards of identity for farina and enriched farina do not secure the purity of foods nor do they inform purchasers of what they are buying.

C. The definitions and standards of identity for farina and enriched farina promote dishonesty and unfair dealing.

IV. The Administrator Cites No Authority Justifying His Order Preventing the Sale of Farina Improved by the Addition of Vitamin D.

ARGUMENT.

I.

THE ADMINISTRATOR'S STANDARDS ARE INVALID BECAUSE UNREASONABLE.

A.

A Definition and Standard of Identity to be Valid must be Reasonable.

The requirement of reasonableness is explicit in the Act.[1] The language of the statute is so clear that citation of authorities would seem unnecessary. However, the authorities clearly support this view. In *Morgan* v. *Nolan*, 3 Fed. Supp. 143, affirmed by the Circuit Court of Appeals for the Seventh Circuit, 69 F. (2d) 471, a case arising under the previous Food and Drug Act, Judge Baltzell said (p. 145):

> "In order that such regulations may be valid, they must be reasonable and consistent with the law under which they are promulgated. *International Ry. Co.* v. *Davidson*, 257 U. S. 506, 42 S. Ct. 179, 66 L. Ed. 341; *Waite* v. *Macy*, 246 U. S. 606, 38 S. Ct. 395, 62 L. Ed. 892.
>
> The Food and Drug Act provides for the branding or labeling of food products, and defines the instances in which food shall be deemed misbranded. Title 21, §10, U. S. C. A. Prior to the amendment of this act in 1930, no authority was delegated to the Secretary of Agriculture to promulgate regulations for the standards of canned food products. Authority is given by

[1] Section 401. "Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a *reasonable* definition and standard of identity, a *reasonable* standard of quality, and/or *reasonable* standards of fill of container; * * *."

such amendments to formulate such regulations. However, *such regulations must be reasonable and consistent with the law which authorizes them.* • • •

The regulations in question, requiring such labeling of plaintiffs food products, are unreasonable and inconsistent with the law under which they were promulgated, and are therefore invalid. *International Ry. Co.* v. *Davidson, supra.*"

In *A. E. Staley Mfg. Co.* v. *Secretary of Agriculture*, 120 F. (2d) 258, a case arising under the statute here involved, the court said (p. 260):

"In exercising the authority granted by the Act now involved, the Secretary must promulgate *reasonable* regulations that are in compliance with the Act, such as will promote honesty and fair dealing in the interest of consumers. *Morgan* v. *Nolan*, (D. C.) 3 F. Supp. 143, and *Nolan* v. *Morgan*, 7th Cir., 69 F. (2d) 471."

A determination of the reasonableness of any action of necessity involves an examination of the consequences of the action. If the advantages gained outweigh the detriment suffered, we say the action is a reasonable one. If, on the other hand, the detriments outweigh the advantages, the action is ordinarily characterized as unreasonable. Having in mind, then, the purposes of the Act and limiting the consideration to facts proved by substantial evidence of record, what are the consequences of the Administrator's standards?

B.

The Addition of the Required Ingredients is an Unreasonable Condition to the Addition of Vitamin D.

The effect of the farina standard, as the Administrator admits and as pointed out in his brief (Adm. Br. 2), is to bar from the market respondent's product, farina with

Vitamin D, by making it a criminal offense to market it. The Administrator argues, however (Adm. Br. 57-8), that respondent is not prevented from selling farina with Vitamin D but is only required to add certain minimum amounts of other ingredients (Vitamin B_1, riboflavin, nicotinic acid and iron), whereupon it may continue marketing the product. In other words, the Administrator's standards impose upon the manufacturer as a condition to adding Vitamin D to his product, the addition of these other four ingredients and the labeling of the product as "enriched."

The imposition of such a condition precedent to the addition of Vitamin D to farina is unreasonable. The Administrator devotes considerable space in his brief (Adm. Br. 18-21) to the proposition that Vitamin B_1, riboflavin, nicotinic acid and iron are beneficial ingredients. Respondent admits this, provided that such ingredients are added in sufficiently substantial amounts. Respondent would go further and say that there are many other nutrients which would be a beneficial addition to any food. Respondent can see no reason, however, for making it a crime to add any one of these beneficial ingredients to a food unless all of the others are also added (R. 165).[2]

There is no scientific basis for the requirement that before Vitamin D may be added to farina these other four ingredients must first be added. There is no showing in the record that there is any relationship between the four required ingredients of the enriched farina standard and Vitamin D. There is no co-action between Vitamin D and any of these required vitamin and mineral ingredients or

[2] Mrs. Potter, a consumer witness, testified (R. 165): "• • • some people may prefer to get their calcium and vitamins and iron in other ways, and I feel that *the consumer should be allowed to get what she wants to* • • •"

any combination thereof. If, for example, the evidence showed that Vitamin D was of no value except when *combined* with one or more of the required ingredients of the enriched farina standard, then there would be a reasonable basis for permitting the addition of Vitamin D to farina only if such other ingredients were also added. But there is no such showing in the record.

On this point the Court below said (R. 687):

> "We say it [the Administrator's order] is unreasonable for the reason that no claim is made of any relationship or co-action between Vitamin D and the other ingredients required in enriched farina. As a result, the consumer who is deficient in Vitamin D only, as is often the case, must buy a product containing vitamins and ingredients which he does not need, or does not want, in order to obtain the benefit of Vitamin D."

But the Administrator argues that the condition is not a burdensome one and feels that the respondent should go along with him on his program. He says (Adm. Br. 57-58):

> "Although the cost of vitamins may appear to be high in terms of dollars per pound (e.g. B_1 costs $700.00 per pound (R. 45, 65)), the minute quantities required results in an insignificant addition to the cost of production."

It is true that the "minute quantities required" may increase the cost but a fraction of a cent a pound. Multiply such fraction of a cent, however, by millions of pounds and the figure may represent the difference between profit and loss on a product. Moreover, to pass this additional cost on to the consumer would defeat the purpose of the Administrator's enrichment program, because it is ordinarily the low income consumer who particularly needs the

vitamins (R. 183).[3] As was said by Dr. Robert Williams (R. 409-410):

> "Obviously the poor of each country, and particularly of the United States, because that is what we are concerned with here today, who suffer most in general from vitamin deficiencies, the moment one adopts a scheme for handling a staple food which adds substantially to its cost, *one tends thereby to limit the consumption of that improved form of foods to the upper classes of the population, and to take it out of the hands of the lower classes of the population.*"

But, regardless of the dollars and cents involved, anything is expensive if its cost is out of proportion to its benefit. Respondent has shown elsewhere in this brief (*infra* p. 59) that the required minima of vitamins and minerals in enriched farina are so low as to provide no definite improvement in the diet.

Respondent concedes that if, under the protection of the Administrator's regulations, it wished to participate in a scheme to defraud the public by adding "minute quantities" of the required ingredients of the enriched farina standard, it could comply with that standard and would not be subject to criminal prosecution for misbranding. It could make substantial capital out of such compliance. It could with impunity advertise that its product was restored to whole wheat values without informing the public that the whole wheat values are so low as to effect no definite im-

[3] The evidence shows and the questions propounded by counsel for the Administrator indicate that *flour* products fortified with vitamins and minerals, substantially as outlined in the enriched farina standard, will sell and actually have sold for higher prices than the non-fortified flour products (R. 55, 90, 97, 165, 334-5, 335, 373, 490). Even the consumers who testified at the hearing below were not so optimistic as to anticipate that enriched flour would sell at no increase in price (R. 490). The Administrator also contemplates such an increase in price, as shown by his brief (Adm. Br. 58).

provement in their diet. It could claim that its product met U. S. standards. It could take advantage of the opportunities the standards afford it to work a fraud on the public. But certainly standards which require this are unreasonable.

Of course, respondent could go further than the standards require and could add a sufficient amount of the required ingredients to accomplish a real improvement of the product, but this would involve great additional expense and would be a major and not a minor alteration of its product.

Respondent submits that consumers have a fundamental right to obtain good, nourishing food for as low a cost as a manufacturer is willing and able to supply it. The Administrator is in effect saying to the mothers of infants and children:

> "For ten years you have been supplying your children with their Vitamin D requirements through the medium of farina fortified with Vitamin D. Henceforth, however, you will not be permitted to have Vitamin D through the medium of farina for your babies and children unless you also have, at increased cost to you, insignificant amounts of Vitamin B_1, riboflavin, nicotinic acid or nicotinic acid amide and iron. You must have these four additional ingredients even though your baby or child is getting ample amounts of those other four ingredients from other sources in his diet."

Respondent submits that it cannot be said to be reasonable to make it a criminal offense, punishable by fine and imprisonment, for a manufacturer *substantially* to improve a food product in one direction by the addition of one vitamin without simultaneously, at increased cost, *negligibly* improving that same product in four different directions by the addition of four separate, unrelated vitamins and minerals.

C.

The Standards Deprive the Consuming Public of an Established Beneficial Product.

As shown above, the effect of the two standards is to bar from the market farina with Vitamin D, by making it a criminal offense to market such product. Farina with Vitamin D added is better and more nutritious than farina as defined in the Administrator's farina standard.[4] Most of the millions of packages of farina sold by respondent during the past ten years has been consumed by infants and growing children (R. 626, 217). The effect of respondent's order is to deprive babies of Vitamin D in their farina, notwithstanding that the record shows, and the Administrator has found as a fact, that there is a Vitamin D deficiency in large numbers of infants and children. It is difficult to see how a standard of identity which reaches such a result can be said to be reasonable.

On this subject the Court below said (R. 687):

> "Another unreasonable result, so we think, is that by the exclusion of vitamin D from petitioner's product, many people will be deprived of this admittedly essential vitamin. This result is none the less real by reason of the suggestion that milk is the most appropriate carrier of vitamin D, and that the majority of consumers (infants and children) who use petitioner's product are also large consumers of milk. There might be merit to this suggestion but for the fact that vitamin D is not a substantial ingredient of milk or any other

[4] The most important use of Vitamin D is in the feeding of the infant and growing child for that vitamin is needed in the prevention or therapy of rickets and in the building of strong bones and teeth (R. 80, 217-18, 361, 368-9). "A deficiency of Vitamin D exists in large numbers of infants and children" (Finding 35, R. 617). Farina "is extensively used as a cereal food for children and in many cases is the only cereal food used during a period of their growth" (Finding 81, R. 626). It is "one of the first so-called solid foods to be fed to babies, starting off at the fourth or fifth month of the baby's life" (R. 217).

natural food product in ordinary use. *Thus, in order to obtain this essential vitamin in milk, it must be added thereto. Looking at the realities of the situation, we think this would mean that very few of the so-called low income group would receive sufficient vitamin D.* Too many of them, no doubt, are without the necessary amount of milk, much less milk to which this vitamin has been added. So, as a final result, the regulations are responsible for a situation whereby a consumer is precluded from obtaining vitamin D alone in connection with farina; he may get it in connection with enriched farina at the option of the manufacturer, or he may get it with his milk, provided he possesses the foresight to see that it is added thereto."

Depriving the consumer of an established beneficial product was recognized as unreasonable and not in the interest of the consumer in *Nolan* v. *Morgan*, 69 F. (2d) 471. That case arose under the McNary-Mapes amendment of July 8, 1930 (21 U. S. C. Section 10) to Section 8 of the U. S. Food and Drug Act of June 30, 1906. Under that amendment the Secretary of Agriculture was authorized to promulgate a "reasonable standard of quality, condition, and/or fill of container for each class of canned food as will, in his judgment, promote honesty and fair dealing in the interest of the consumer." He was further authorized to prescribe a form of label statement for canned food falling below the standard promulgated by him. In that case the standard set for canned peas was immature green peas, and the regulations required the appellee to label his peas, which were prepared from soaked dry ripe peas, with the legend "Below U. S. Standard. Low quality but not illegal. Soaked dry peas." The Court, finding that the appellee's product was a wholesome and nutritious food, held the regulations of the Secretary unreasonable, saying (pp. 473-4):

"* * * to say that canned ripe peas are an inferior grade of canned immature peas is, in our judg-

ment, at once illogical, unreasonable, and unfair * * *

> As stated in the amendment itself, the regulations to be made under it should 'promote honesty and fair dealing *in the interest of the consumer*,' and the Secretary of Agriculture is authorized, from time to time, to make modifications therein, 'as in his judgment, honesty and fair dealing *in the interest of the consumer* may require.' **It cannot be in the interest of the consumer to drive from the market this useful and cheaper product through branding it so the public will not buy it.**" (Italics are the Court's.)

If it is unreasonable to drive wholesome food from the market by a regulation requiring offensive labeling, it is manifestly unreasonable to drive similar food from the market by a standard of identity which absolutely prohibits the sale of the product because it is a better food than the one not recognized by the standard. The Administrator's standard is much more severe than was the standard of quality in the *Nolan* case. In that case the Secretary of Agriculture had the argument that the appellee could continue to market his product provided he employed the proper label, but in the respondent's case it cannot legally continue to market its farina no matter what kind of label it uses. The standard does not even permit it to use a "crepe" label.

Millions of packages of respondent's product are sold each year (R. 218). This is ample proof of the demand for respondent's product by the consumer. The people who are consuming these millions of packages are obtaining 100% of their minimum daily requirement of Vitamin D every day they consume a serving. It is certainly unreasonable to deprive these consumers of the product which they have shown during the past ten years that they desire and need and to which they are entitled. The language of Judge Baltzell in the lower court decision in the *Morgan*

case (3 Fed. Supp. 143, 145) is particularly applicable here.

> "The rapid increase in the amount of dry peas placed upon the market by plaintiffs within the past few years is ample proof of the demand for that particular product by the consumer. To require plaintiffs to comply with such regulations will not only seriously damage their business, *but will deprive the consumer of the product which he desires, and to which he is entitled.*"

D.

The Administrator's Order Will Increase the Present Deficiency of Vitamin D in Infants and Children.

As has been pointed out, the Administrator found that (R. 617):

> "A deficiency of Vitamin D exists in large numbers of infants and children."

The deficiency is greatest in families of low income who cannot afford to buy cod liver oil or other specifics (R. 83, 427-28). An example is disclosed by the spot map showing the distribution of cases on the rachitic studies through the city of Detroit in 1939 (R. 549). In reference to this, Dr. Scott pointed out that the disease was largely centered in the slum areas. He made clear the necessity for supplying Vitamin D in some commonly consumed food (R. 428). Farina is sometimes known as purified middlings (R. 220). It is cheap. Milk, also a good carrier, is relatively expensive.

At record 428-29 reference is made to studies of rickets conducted in Portland, Oregon, and in San Diego, California. These were taken from a publication, The American Journal of Disease of Children, of December, 1937 (R. 428). In Portland, of the children examined, 95% showed signs

of rickets; and in San Diego 73%. The failure of sunshine in San Diego would not seem to match the failure of sunshine among the tenements in our large industrial centers. Obviously, there is a plain necessity for Vitamin D in the cheaper available and used foods.

The effect of the Administrator's order in striking down respondent's farina with Vitamin D added, must be to increase, rather than to diminish, the deficiency of Vitamin D that even now, as the Administrator found, exists in large numbers of infants and children. It was not only wholly unnecessary to do this, but the order effecting such result is unreasonable. Shall this source of sufficient Vitamin D, to the extent of millions of packages per annum, be now removed because of an alleged confusion that in ten years' time has never occurred in a solitary instance, as far as this record shows?

E.

The Standards Destroy Respondent's Established Business in Farina Fortified With Vitamin D.

Respondent has spent ten years in building up a business in the improved food product, farina with Vitamin D (R. 218). The product has been made widely available (R. 218). It is submitted that any definition and standard of identity which destroys an existing business in an established beneficial food product is on its face not "reasonable" within the meaning of the Act. In *Twin City Milk Producer's Assn., et al. v. McNutt*, 122 F. (2d) 564, the Circuit Court of Appeals for the Eighth Circuit had before it on review a definition and standard of identity promulgated by the Administration for "dried skim milk." The petitioner in that case attacked the name referred to in the standard as being unreasonable, urging in lieu thereof the name "dry

milk solids not over 1½% fat." In sustaining the Administrator on that phase of the case, the court said (p. 568):

> "While he (the Administrator) would have *no right to adopt a designation for the purpose of destroying trade in a legitimate food product*, there could ordinarily be no arbitrariness involved in using the common or usual name of such a product for regulation purposes."

So here, paraphrasing the Court's language, the Administrator had no right to adopt a standard for the purpose of *or with the necessary effect of* destroying trade in the respondent's legitimate food product.

That a definition and standard of identity for a food which destroys a going business in a legitimate, wholesome food product is not contemplated by the Act is also shown by the Senate Committee report on the bill eventuating into the Act. That report stated:

> "This bill has been prepared with three basic principles in mind; first, it must not weaken the existing laws; second, it must strengthen and extends the law's protection of the consumer; and, third, *it must impose on honest industrial enterprise no hardship which is unnecessary or unjustified in the public interest.*" Senate Report No. 152; 7th Congress, March 8, 1937.

The Administrator argues that it is immaterial that a particular manufacturer must change his methods or product or even that some products may be driven from the market (Adm. Br. 57). In support of this statement respondent cites a number of cases which, however, as will be pointed out in this brief (*infra* pp. 33-4), involve the question of whether Congress or a state legislature may do

the acts complained of.[5] What is reasonable for Congress or state legislature may not be reasonable for administrative action and is not reasonable in this case, in view of the declared purpose of the Act.

Respondent cites the case of *Houston* v. *St. Louis Independent Packing Company*, 249 U. S. 479, 484 (Adm. Br. 47-58), as demonstrating that an administrative agency may bar a food from the market. Examination of that case, however, reveals that it was a case of *dilution* of sausage by the addition of cereal. Surely the Administrator does not object to Vitamin D on the ground that it dilutes farina. So also examination of the case of *United States* v. *Carolene Products Co.*, 304 U. S. 144, 149 (Adm. Br. 57) reveals that it involved the adulteration of milk by the substitution of cocoanut oil for milk fat.[6] Admittedly respondent does not claim that farina is being adulterated by the addition of Vitamin D.

The Administrator's position that the fact that respondent's product has been accorded consumer acceptance and approval should not be considered is strikingly inconsistent with the Administrator's argument in *Staley Manufacturing Company* v. *Secretary of Agriculture*, 120 F. (2d) 258, that there the petitioner's product (corn syrup) was not entitled to be named as an optional ingredient in sweetened condensed milk *because it had no prior commercial use.*

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[5] *Mugler* v. *Kansas*, 123 U. S. 623, 628, 633; *Powell* v. *Pennsylvania*, 127 U. S. 678, 683, 685; *Hebe Co.* v. *Shaw*, 248 U. S. 297, 302-303; *United States* v. *Carolene Products Co.*, 304 U. S. 144, 151.

[6] The Circuit Court of Appeals, speaking of the Carolene Products case, said (R. 687-8): "The court, in commenting upon the Congressional hearings, on page 149 of 304 U. S., page 781 of 58 S. Ct., said: '• • • Both committees concluded, as the statute itself declares, that the use of filled milk as a substitute for pure milk is generally injurious to health and facilitates fraud on the public.'"

F.

It Is Unreasonable to Exclude Vitamin D as an Optional Ingredient from Farina and Permit It as an Optional Ingredient in Enriched Farina.

It has heretofore been pointed out that there is no coaction or joint action between Vitamin D and the required ingredients Vitamin B_1, riboflavin, nocotinic acid and iron of the enriched farina standard. Consequently, if it is reasonable to permit Vitamin D to be added to the product enriched farina as an optional ingredient, it is on the face of it unreasonable to exclude Vitamin D as an optional ingredient from the product farina.

The Administrator's principal point for the exclusion of Vitamin D from farina is the argument hereinafter answered that consumers will be confused and misled by permitting such practice. It will be shown that no one has ever been confused or misled by respondent's practice and that there is no evidence of any likelihood or even possibility of such confusion occurring (*infra* pp. 40-46). If such confusion does or will exist as a result of adding Vitamin D to farina, it would seem that exactly the same confusion would occur as a result of the addition of Vitamin D to so-called enriched farina. If the Administrator's theory on confusion is right, why does he permit Vitamin D *or anything else optionally* to be added to his "enriched farina?" This will promote confusion just as much as the addition of Vitamin D to farina. In both cases, the only way the consumer will know whether or not Vitamin D is in the product will be by the *label declaration*. If the consumer cannot read or understand what he reads; he will never know; if he can read and understand, and does so, he will know *in either case*.

The Standards Prohibit the Improvement of Farina.

Another unreasonable consequence of the farina standard is that it puts a ceiling over quality rather than a floor under it. In establishing his standard of *identity* the Administrator has established an unreasonable standard of *quality*. The result of his order is that any manufacturer who attempts to make his product better than that of his competitor subjects himself to criminal prosecution unless his improvement coincides exactly with the improvements specified for him by the Administrator. Clearly such a result was not intended by the Act. Clearly the standards reaching such a result are not reasonable.

But the Administrator argues that the effect of the decision below is to require every definition and standard of identity to include a blanket clause permitting any non-deleterious variation which is disclosed by the label (Adm. Br. 31, 42).[7]

This conclusion does not follow. Obviously the allowance of the addition of all non-deleterious ingredients, regardless of whether they are of added benefit to the product, would result in dilution of the product. For instance, water is a non-deleterious ingredient, yet no one has suggested that the addition of water to a standardized product be permitted on this account. The Administrator is, and should be, permitted to prevent dilution.[8] He may do so by the

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[7] This is part of Administrator's general argument to the effect that the standards are intended to be exclusive (Adm. Br. 39-45). He says (Adm. Br. 33): "This power to permit optional ingredients cannot be construed as an obligation to permit any disclosed non-deleterious addition, or, in other words, to exclude only deleterious or concealed ingredients, for to do so renders identity standards nugatory."

[8] See respondent's discussion of *Houston v. St. Louis Packing Co.*, 249 U. S. 479 (*supra* p. 24).

simple means of restricting optional ingredients to those which will *improve* the product.

Respondent has not asked for the inclusion of Vitamin D as an optional ingredient in farina merely because it is non-deleterious, nor even because it is a beneficial ingredient. Its inclusion is requested because its addition *makes the finished product a better product.*

Moreover, Vitamin D is not merely an idly "suggested" addition. It is not a theoretical improvement. It is an accomplished improvement with over ten years of commercial practice behind it. Its inclusion was supported by substantial proof of record at the public hearing held by the Administrator for the express purpose of receiving such proofs. Of what purpose is the public hearing if the Administrator is permitted to ignore the evidence there adduced? As was said in *A. E. Staley Mfg. Co.* v. *Secretary of Agriculture*, 120 F. (2d) 258, 261:

> "Certainly the right to present evidence is a barren one if the trier of fact fails to consider it."

It is submitted, therefore, that neither the decision of the Circuit Court of Appeals nor respondent's contention implies the conclusion that all non-deleterious ingredients would have to be included. What the Circuit Court of Appeals did say and what respondent now says is that the standard for farina is unreasonable in excluding Vitamin D in view of the evidence in the case.

B.

The Administrator's Reasons for the Exclusion of Vitamin D from Farina Are Untenable.

The above examination of the consequences of the Administrator's standards has demonstrated that they impose an unreasonable condition on the addition of Vitamin D to

farina, that they will deprive the consuming public of the established beneficial product, that they will increase the Vitamin D deficiency in infants and children, that they will destroy respondent's established business in its farina product, and that they will prohibit improvement of the standardized product. What advantages then does the Administrator claim which will outweigh these detriments and make the standards reasonable?

1. *Honesty and fair dealing.*

The Administrator claims that the standards will promote honesty and fair dealing. Respondent, however, will demonstrate (*infra* pp. 56-62) that exactly the reverse will be true and that the standards will in fact promote dishonesty and unfair dealing.

2. *The instinct theory.*

The Administrator contends that Vitamin B should be excluded from farina because it does not occur in significant quantities in the whole wheat berry (Adm. Br. 20). Thus he justifies his enriched farina standard requiring Vitamin B_1, riboflavin, nicotinic acid and iron on the ground that they are found in the whole wheat berry (Adm. Br. 55). He claims that his standards are not artificial because they are "an accommodation to existing natural, historical, and dietary phenomena" (Adm. Br. 55). Apparently the genesis of the idea that enrichment of farina should be limited to enrichment in those nutrients contained in the original wheat berry is the "instinct theory" of Dr. Russell W. Wilder. He said (R. 102):

> "It is not impossible that subconsciously when we need Vitamin A or one of the other fat-soluble vitamins, we turn to a fat to get it. I cannot offer proof of that, but it is a suggestion, and that when we subconsciously have a feeling that we want some Vitamin C, we don't

> turn to fat for Vitamin C, we subconsciously ask for an orange, or some tomato juice; and likewise when we subconsciously feel the need for any part of the Vitamin B complex, particularly for the thiamin of the Vitamin B complex, we turn to the cereal grains."

This theory would lead logically to the surprising conclusion that when one needs Vitamin D, he would experience a subconscious seeking for cod liver oil. But perhaps this unrealistic conclusion has been avoided by Doctor Wilder's admission on cross-examination that the human animal instincts have undergone such serious deterioration that instinct could probably not be relied upon (R. 112).

The fallacy of the instinct theory and of the Administrator's argument was pointed out by Doctor Sherwood. He said (R. 146):

> "Obviously, the wheat kernel is produced to propagate the wheat plant. * * * And the mere fact that it has certain of these vitamins and minerals present in certain proportions does not indicate a proper balance for us."

He also said (R. 147):

> "* * * the lumberman saws the tree to fit the house and doesn't build the house to fit the tree."

The theory was entirely exploded by the Administrator's own witness, Doctor Nelson, Chief of the Vitamin Division of the Food and Drug Administration. He pointed out that if instinct could be depended upon, people would subconsciously choose whole wheat bread, and the whole Vitamin B enrichment program would be pointless (R. 182).

Clearly the ingredients of the standardized food should be determined by the necessity for those ingredients in the diet, with special consideration as to how that food fits into the diet. The vitamins or minerals contained by the food in its natural state have nothing whatsoever to

do with the question. Respondent adds Vitamin D to farina because there is a marked deficiency of Vitamin D in the diets of most people, and particularly in the diets of infants and children. Its function is to promote the assimilation by the body of calcium and phosphorus, which are contained in other foods, particularly in milk, with which farina is usually consumed. "* * * the only natural food designed for human nutrition is mother's milk" (R. 45). Accordingly, blind loyalty to existing natural phenomena cannot be considered reasonable.

Respondent has no objection to the inclusion of the Vitamin B group as additional *optional* ingredients in the farina standard. This group is composed of beneficial ingredients, and if the Administrator is satisfied that substantial evidence supports their inclusion as optional ingredients, he should so provide. The record shows that a deficiency of one of the Vitamin B complex is usually accompanied by deficiency in the others (R. 366, 388). Accordingly, respondent would be in favor of a ruling that no member of the Vitamin B complex should be added unless other members of that group are also added. This fact has nothing to do with Vitamin D. Vitamin D does not exist to an appreciable extent in the normal diet. Accordingly, a Vitamin D deficiency may occur—and in modern city life with its smoke, dust, and artificial light does occur—in spite of a well balanced diet. There is no coaction between Vitamin D and the Vitamin B complex (*supra* pp. 14-15). They are independent. There is no chemical, nutritive, or other reason why the addition of one should be a condition precedent to the addition of another.

3. *Facility of enforcement.*

The Administrator argues that the standards must be exclusionary or they will be valueless (Adm. Br. 30-45).

With this respondent has agreed (*supra* pp. 26-7).[9] The Administrator says that this is necessary to permit the standards to be enforced to prevent dilution or adulteration (Adm. Br. 36-40). Again respondent agrees.[10] But all of this gives no support to the Administrator's denial of the right of consumers to have farina improved with Vitamin D. The provision for the inclusion of Vitamin D as an optional ingredient would not hinder the Administrator's enforcement of the law to prevent dilution or adulteration. No one will dilute or adulterate farina worth a few cents a pound with vitamins worth hundreds of times as much.

4. *Difficulty in drawing the line.*

The Administrator says that his problem is one of where to draw the line and that in testing the reasonableness of the line which is drawn, the issue cannot be whether the line may have been drawn at some other point (Adm. Br. 53). But this line-drawing cannot be treated as casually as that.[11] There are millions of consumers entitled to fair consideration and respondent has a business at stake. Respondent, at not inconsiderable cost in time, effort, and money sent witnesses to the Administrator's hearings and proved its case. If the line is drawn to exclude respondent's

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[9] If the farina standard were not exclusionary then obviously respondent could add Vitamin D to its farina and the present controversy would never have arisen.

[10] The Administrator cites *U. S. v. Ten Cases, More or Less, Bred Spred*, 49 F. (2d) 87, which was a case of dilution. The Administrator should, and does, have the right under the Act to prevent dilution.

[11] The Administrator says: "Reasonable men basing their action on the same facts and findings could arrive at entirely different regulations, none of which could be properly characterized as arbitrary, whimsical, or unreasonable" (Adm. Br. 54). As is pointed out (*infra* p. 34) legislative acts are valid only unless "arbitrary" or "whimsical," but the Administrator is not given such a latitude. He must make his regulations reasonable (*supra* pp. 12-13).

product and there is not substantial evidence to support such action as reasonable, the standards should be set aside. The Administrator is charged with quasi-judicial functions and must perform his duties with care and conscientious consideration for the rights involved. As was said by Chief Justice Hughes in *Morgan* v. *United States*, 304 U. S. 1; 22:

> "The maintenance of proper standards on the part of administrative agencies in the performance of their quasi-judicial functions is of the highest importance and in no way cripples or embarrasses the exercise of their appropriate authority. On the contrary, it is in their manifest interest. For, as we said at the outset, if these multiplying agencies deemed to be necessary in our complex society are to serve the purposes for which they are created and endowed with vast powers, they must accredit themselves by acting in accordance with the cherished judicial tradition embodying the basic concepts of fair play."

But the Administrator says that "presumably, if Vitamin D were entitled to be included as an optional ingredient, a multitude of other non-deleterious ingredients has equal claim to optional inclusion" (Adm. Br. 54n).[12] The Administrator does not contend that this statement is supported by the record. If it is, however—if substantial evidence of record indicates that other ingredients are entitled to the same treatment as Vitamin D—then the Administrator should have included them and his exclusion of them should have been corrected if appeal had been taken from his order within the proper time. Respondent submits that *if there is substantial evidence that an ingredient will improve the product, it is unreasonable to exclude it.*

[12] It has been pointed out that the right of Vitamin D to be included as an optional ingredient is not based upon the mere fact that it is a non-deleterious ingredient (*supra* p. 27). That right is based upon improvement of the product, consumer need and prior use.

Reviewing, then, the consequences of the Administrator's standards, what is the result? The detriments are manifest. The standards impose an unreasonable condition to the addition of Vitamin D. They will deprive the consuming public of an established beneficial product. They will increase an existing Vitamin D deficiency. They will destroy respondent's established business and its product. They will prohibit improvement of the food. Against these detriments the Administrator claims outweighing advantages. He says his standards are consistent with an instinct theory which has been shown to be fallacious by testimony which the Administrator himself adduced. He claims they will facilitate enforcement, which has been shown to be untenable. And finally he has confessed weakly to a difficulty in drawing the line. It is submitted that the detriments suffered by far outweigh the advantages claimed. The standards are therefore unreasonable.

I.

The Administrator's Determination of Reasonableness Is Limited by the Principles and Limitations of the Act.

The word "reasonableness" is, of course, a relative term. It involves a consideration of the purposes to be accomplished. It also involves a consideration in the light of certain given facts. Accordingly, the determination of reasonableness of the standards in question is interdependent with the consideration of the purpose of the Act and of the substantial evidence upon which the determination must be made. These two subjects will hereinafter be considered (*infra* pp. 51-64; 38-51).

It is submitted that the Administrator, in claiming wide latitude in the determination of reasonableness, has lost sight of the other requirements of the Act. In support of his claim of unrestricted discretion in the determination

of reasonableness, he has cited a number of cases (Adm. Br. 57).[13] Without exception, however, these cases relate to the constitutional powers of Congress or state legislatures to enact the statutes in question. Of course, the test applied in these cases was the test of reasonableness, but the Administrator cannot claim the latitude which Congress enjoys in making the laws. If the Administrator's power can be broad as that of Congress, then unlawful delegation of power would never be a valid objection to any legislation.

The power of Congress or of a state legislature to determine reasonableness is very broad. In *Southern Garment Manufacturers Association* v. *Fleming*, 122 F. (2d) 622, 632, the Court said:

> "Now it should be remembered that the legislative could meet and without any consideration or deliberation put a and b into class m and c into class n. And when the problem got to the courts the issue would still be, is the classification arbitrary, or is there any relation between method and end, and not is the grouping wise."

In *Hebe Co.* v. *Shaw*, 248 U. S. 297, 303, Justice Holmes, speaking for this Court, said:

> "The inquiry must be whether, considering the end in view, the statute passes the bounds of reason and assumes the character of a merely arbitrary fiat."

In *Powell* v. *Pennsylvania*, 127 U. S. 678, 684, this Court quoted with approval from its opinion in *Sinking Fund Cases*, 99 U. S. 700, 718, as follows:

> "Every possible presumption is in favor of the validity of a statute, and this continues until the contrary is shown beyond a rational doubt."

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[13] *Mugler* v. *Kansas*, 123 U. S. 623, 628-633; *Powell* v. *Pennsylvania*, 127 U. S. 678, 683-684; *Hebe Co.* v. *Shaw*, 248 U. S. 297, 302-303; *U. S.* v. *Carolene Products Co.*, 304 U. S. 144, 151.

What, then, is the difference between the Administrator's power to determine reasonableness and that of Congress? In *Panama Refining Co.* v. *Ryan*, 293 U. S. 388, 421, this Court, holding that section 9 (c) of the National Industrial Recovery Act provided for an unlawful delegation of power, said:

> "The Constitution has never been regarded as denying to the Congress the necessary resources of flexibility and practicality, which will enable it to perform its function in laying down policies and establishing standards; while leaving to selected instrumentalities the making of subordinate rules *within prescribed limits* and the determination of facts to which the policy as declared by the legislature is to apply. • • • But the constant recognition of the necessity and validity of such provisions, and the wide range of administrative authority which has been developed by means of them, *cannot be allowed to obscure the limitations* of the authority to delegate, if our constitutional system is to be maintained."

The Court then reviewed a number of cases to show that Congress must set up "primary standards" or "intelligible principles," and referring to the statute under consideration by it, said (p. 430):

> "• • • Congress has declared no policy, has established no standard, has laid down no rule. There is no requirement, no definition of circumstances and conditions in which the transportation is to be allowed or prohibited."

In *Schechter Corp.* v. *United States*, 295 U. S. 495, 537-538, this Court said:

> "• • • Congress cannot delegate legislative power to the President to exercise an unfettered discretion to make whatever laws he thinks may be needed or

advisable for the rehabilitation and expansion of trade or industry."

Respondent has not argued that the Federal Food, Drug and Cosmetic Act makes an unconstitutional delegation of authority to the Administrator. The reason that this argument has not been made is that respondent recognizes that Congress has attempted in the Act to preclude the charge of unlawful delegation, by carefully declaring the policy of the Act and by prescribing standards, principles, and limitations governing the exercise of power by the Administrator. The policy of the Act is to "promote honesty and fair dealing in the interest of consumers." As was said in the case of *A. E. Staley Mfg. Co.* v. *Secretary of Agriculture*, 120 F. (2d) 258, this means that the purpose is to secure purity of foods and to inform purchasers of what they are buying. The aim of *purity* and *information*, then, constitutes the policy, the principle, the standard of the Act.

But there are limitations too. The Administrator is not given the "unfettered discretion" condemned in the *Schechter* case. He must "hold a public hearing" after "appropriate notice"; his order must be based only on "substantial evidence of record," and must set forth "detailed findings of fact."

The right of Congress to legislate is not so restricted. Legislation must be reasonable, but its reasonableness is not measured in the light of the above limitations or of predeclared policy.

The Administrator must confine his activities to the promotion of the policy of the Act as above defined. Within the limitations set forth, he may do three things: (1) Fix reasonable definitions and standards of identity; (2) fix reasonable standards of quality; (3) fix reasonable stan-

dards of fill of container. For what purpose may he do these things? He may fix definitions and standards of identity so that consumers will get what they pay for, so that sellers won't lie about their products. He may fix standards of quality so that sellers will not dilute or adulterate their products. He may fix standards of fill of container so that sellers will not sell twelve ounces in a container appearing to hold a pound.

These aims are commendable. They are within the power grant of the Act. If the Administrator's action in respect to farina goes beyond this, his order is invalid. Respondent is as anxious to be protected against cheating competitors as is any other honest manufacturer. But respondent cannot agree that the Administrator has the power to bar from the market any food which he, in his uncontrolled discretion, may see fit to outlaw, without regard to whether that food is wholesome or deleterious, and then to seek to justify his action on the ground that Congress could do this.

The Congressional Act is fair. But the Administrator in his determination of reasonableness may not disregard its declared policy; its principle, its standards, and its limitations by the assertion of powers tantamount to those possessed by Congress. If he does so, he construes the Act to an unconstitutional result. It is not enough that legislation contain the requisite language to make it constitutional. The courts also have a duty to administer it to a constitutional result. *Sawn* v. *Williams*, 273 Mich. 402, 263 N. W. 407, 409. Otherwise the Act would be invalid as an unconstitutional delegation of powers. This Court has said that if a doubt arises as to a constitutional point, that construction should be adopted which avoids the doubt. *U. S.* v. *Shreveport Grain & Elevator Co.*, 287 U. S. 77, 82; *Lewellyn* v. *Frick*, 268 U. S. 238, 251, citing *Panama R. R. Co.* v. *Johnson*, 264 U. S. 375, 390.

Respondent submits that the Act does not give to the Administrator the uncontrolled discretion in the determination of reasonableness which he claims. The distinction between "reasonable" as applied to legislation and "reasonable" as applied to the Administrator's order may not be overlooked. As was said by the Court below, in commenting upon *U. S. v. Carolene Products Co.*, 304 U. S. 144 (R. 688):

> "Furthermore, the court in the Carolene case was dealing with the power of Congress, while here we are considering the authority which Congress has conferred upon the Administrator, and the reasonableness of his action."

II.

THE STANDARDS ARE INVALID BECAUSE NOT BASED UPON SUBSTANTIAL EVIDENCE OF RECORD.

A.

A Definition and Standard of Identity to be Valid Must Be Based upon Substantial Evidence.

Section 701 (e) of the Act provides in part as follows (21 U. S. C. A. 371 (e)):

> "The Administrator shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based."

The requirement of "substantial evidence" is not new in administrative law. The term in general has been said to mean such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. It must be enough to justify, in a jury trial, a refusal to direct a

verdict when the conclusion sought to be drawn from it is one of fact for the jury.[1]

Manifestly, when the statutory requirement of substantial evidence in support of the order is not met, the order is invalid. And if the only substantial evidence adduced is contrary to the order, it is even more clear that the order cannot be sustained. For evidence cannot be ignored. In this connection, in the case of *A. E. Staley Manufacturing Company* v. *Secretary of Agriculture*, 120 F. (2d) 258, the Court said (p. 261):

> "The petitioner adduced evidence at the hearing, which is undisputed, which appears to constitute 'substantial evidence of record,' but which the Secretary of Agriculture ignores completely in its order. The statute provides that the Secretary "shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based' 21 U. S. C. A. 371 (e).
>
> "In effect petitioner complained that the administrative fact finder did not consider the evidence in question. *Certainly the right to present evidence is a barren one if the trier of fact fails to consider it. Morgan* v. *United States*, 298 U. S. 468, 304 U. S. 1."

Accordingly, in the instant case, if any part of the standard, including the omission of any suggested optional ingredient, is not supported by substantial evidence, the standard is invalid. And if substantial evidence was adduced to support the inclusion of an optional ingredient, the standard is even more clearly invalid, if it fails to in-

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[1] *N. L. R. B.* v. *Columbian Enameling Company*, 306 U. S. 292, 299-300 (1939); *Consolidated Edison Company* v. *N. L. R. B.*, 305 U. S. 197, 229 (1938); *Hamilton Brown Shoe Company* v. *N. L. R. B.*, 104 F. (2d) 49, 52 (8 C. C. A., 1939); *N. L. R. B.* v. *Louisville Refining Company*, 102 F. (2d), 678, 680 (6 C. C. A. 1939); *Montgomery Ward & Co.* v. *N. L. R. B.*, 107 F. (2d) 555, 558 (7 C. C. A. 1939); *Cupples Co., Mfrs.* v. *N. L. R. B.*, 106 F. (2d) 100, 114 (8 C. C. A. 1939); *N. L. R. B.* v. *Empire Furniture Corp.*, 107 F. (2d) 92, 95 (6 C. C. A. 1939).

clude such optional ingredient—if the Administrator merely ignored the testimony on that question.

B.

Exclusion of Vitamin D from the Farina Standard is not supported by Substantial Evidence of Record.

Apparently the Administrator excluded Vitamin D from the standard for farina and included it in the standard for enriched farina for two reasons. The first of these reasons seems to be a vague feeling that the proper standard of enrichment is the standard set by nature in the formation of the wheat berry itself (Adm. Br. 20-22, 55-56). The fallacy of this reasoning is discussed elsewhere in this brief (*supra* pp. 28-30). And, of course, the Administrator himself has admitted the fallacy by including Vitamin D in the enriched farina standard, thereby abandoning his "restoration" theory of enrichment and admitting the propriety of the addition of Vitamin D (R. 637-8).

The other basis for relegating Vitamin D to the artificial enriched farina standard is the claim of the Administrator that optional[1] enrichment would tend to confuse and mislead consumers. This claim is based upon findings 36, 37, and 39, which in turn are based upon testimony relating to flour. The Administrator attempted to make these findings apply to farina by the easy process of "incorporation by reference" (Finding 83, R. 626). But in so doing he

[1] The Administrator refers to "partial" enrichment. The word "partial" is confusing. Respondent believes that the standard should require a *quantitative* minimum of any vitamin that is added; i.e., if Vitamin D is added, it should be added in such quantity as will effect a definite improvement in the product (see respondent's argument that the Administrator's standard for enriched farina is a potential instrument of fraud because its minima are too low, *infra* pp. 59-61). Respondent objects to a requirement of *qualitative* minima, i.e., the contention that B_1, etc., must be added if D is to be added. Qualitative enrichment is always "partial," because no one expects to make of farina a perfect food containing all the nutrients required by the human body. Hence the Administrator's enriched farina standard specifies "partial" enrichment both quantitatively and qualitatively.

ignored the fact that there was no evidence to support such findings as to farina.

And even as to flour, the testimony is no support whatsoever for the Administrator's findings of a likelihood of confusion. The Administrator's numerous references to the record on this point (Adm. Br. 23-26), may create the impression that there was testimony in support of these findings. Of the four "consumer representatives" whose testimony was cited by the Administrator (Adm. Br. 23), *none testified that optional enrichment would cause confusion*. One testified that she opposed grouping differently enriched flours *under one name*, and that the adding of any one or more vitamins to a flour *would not cause confusion if shown on the label*, thus supporting respondent's position and commercial practices.[2]

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[2] This witness was Miss Ross whose testimony is heavily relied upon but incompletely quoted by the Administrator (Adm. Br. 25-26). In expressing her opinion on possible consumer confusion Miss Ross, as her testimony on pages 496-97 of the record clearly shows, was objecting to the grouping under one common name, such as "fortified flour" or "enriched flour," of a multitude of products each fortified with different vitamins or minerals and each containing perhaps different amounts of such vitamins or minerals. Referring to a flour to which, for example, only one vitamin had been added, she said (R. 496):

> "• • • flour with only one of these factors should we feel not be permitted to make use of the term "fortified" or whatever term is applied to flours."

Her testimony affirmatively shows, however, that she saw no possibility of consumer confusion in the enrichment of foods with single vitamins, if such fortification was properly indicated on the label. She testified that the added ingredients should be listed (R. 497):

> "on a less fortified product, which would not use that one word [such as "fortified" or "enriched"], *but would have some other indication of what other ingredients had been added.*"

Further, when Miss Ross testified regarding the consumer's "truly difficult position" (Adm. Br. 26), she was discussing the desirability of adopting *uniform nomenclature* for the various vitamins, not their use in the enrichment of foods (R. 492). This has no bearing on the question of possible confusion by the *fact* of optional enrichment.

Another expressed her "fear," *not of the addition of a single vitamin, but of the Administrator's restoration theory* (R. 116).[3] Another, representing the American Association of University Women, an organization of 68,000 consumers, wanted labeling which would tell her what she would get, so that she could take her choice (R. 164).[4] She testified (R. 165):

> "There are very definite advantages to a reinforced flour, *but some people may prefer to get their calcium and vitamins and iron in other ways, and I feel that the consumer should be allowed to get what she wants to* . . . ."

The last witness also wanted identification (R. 175).[5]

The Administrator also cited the testimony of two "disinterested scientists" (Adm. Br. 23). The first is Doctor Wilder, the proponent of the "instinct theory" (*supra* pp. 28-30). We find no expression of fear of confusion in his cited testimony. The other is Doctor Williams who suggested that if a vitamin is added, it should be added in sufficient amounts (R. 409).[6]

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[3] "I fear that if Vitamin B_1 and other substances present in whole wheat are added to wheat flour for general consumption, we shall witness a tremendous advertising campaign about the marvelous effects of these elements, which will make people overconfident about the value of these products and cause them to forget that *whole wheat flour is still the only complete flour.*"

[4] Respondent gives her such labeling. The Administrator's standards do not.

[5] "The problem, as we see it, is how close you are going to identify it. I can't say the proposals of the industry made will make it possible to identify such products if they are all included in one standard of identity."

[6] Respondent agrees. It adds 100% of the minimum daily requirements of Vitamin D.

The testimony of two "industry representatives" was also cited (Adm. Br. 23). One of them thought there should be *minimum levels* to eliminate the danger of numerous flours with numerous values (R. 147). The other expressed no fear of confusion by the addition of different kinds of vitamins. He merely pointed out that there was difficulty in telling the people how much of a vitamin they were getting in a product (R. 311).

Then the Administrator cites the testimony of two "federal food and drug experts" (Adm. Br. 23). One of them[7] opposed a standard for a multiplicity of kinds of supplemented flours on the ground of confusion (R. 177).[8] As in the case of Miss Ross, Miss Chatfield's fear of confusion was based upon grouping differently fortified or enriched flours *under one name*, as shown by her testimony quoted in footnote 8. The other federal food and drug expert, Doctor Nelson, Chief of the Vitamin Division of the Food and Drug Administration, was in favor of a separate standard for flour *containing one or more optional ingre-*

[7] Charlotte Chatfield of the Bureau of Home Economics.

[8] The basis of Miss Chatfield's prognostication of confusion is shown by her later testimony on cross examination. She testified (R. 178):

> "Q. Miss Chatfield, do you think if a flour is fortified in some respects, in one or more respects, and is fortified or below the restoration point in other respects, it could be called a fortified flour and that be descriptive?
>
> A. I think that that would not be in line with the suggestion I was trying to make. It would make too many kinds of flours *that could be called by a single name, for example, "fortified flour."* • • • One manufacturer supplies one mineral and another one supplies another; and certain others supply one or another vitamin. *And if each of those is called "fortified flour," it would be extremely confusing.*"

Obviously if a host of different products were all designated in the same way, as "fortified farina" or "enriched farina," there would be confusion. But respondent does not call its product "enriched farina" and has no intention of so doing. Its product is called "Quaker Farina Wheat Cereal enriched with Vitamin D."

dients (R. 183, 193).[9] He did not propose a standard containing *required* ingredients as *a condition to the addition of the optional ones.*

The Administrator lifted from their contexts the portions of the testimony he quoted: It is important that consideration be given to what these witnesses were talking about. First, they were speaking of flour, not of farina. There had recently been placed on the market a great number of flours enriched with one or more elements (Finding 36, R. 617-18). These flours were being described by a variety of names. It was to the matter of avoiding confusion *between names* and of informing the purchaser as to what vitamins she was being given, that these witnesses were primarily addressing themselves. Farina was not in their minds. The record reveals only two farinas with added vitamins (Report of Presiding Officer, R. 562).[10] Farina did not receive the consideration to which it was entitled.[11] It was forced into the flour

[9] "Q. If we have a standard for enriched flour, in order to comply with the standard for enriched flour, would it have to contain all these vitamins you have indicated, or would it be an enriched flour if it contained any one or more of the optional ingredients? I am not clear as to just what your idea is.

"A. *It would be such a flour with one or more of the optional ingredients*" (R. 193).

[10] The Administrator says there were six or seven (Adm. Br. 23). This is incorrect.

[11] Finding 2: "Flour is used primarily for making white bread and biscuit, and consumers of flour normally expect that it will be suitable for these purposes" (R. 610-1). Finding 81: "Farina is used as a breakfast food and as an ingredient of macaroni products. • • • it is extensively used as a cereal food for children and in many cases is the only cereal food used during a period of their growth." (R. 626).

standards without consideration of its differences from flour.

Further, the testimony of these witnesses *as to flour* does not rise to the dignity of evidence even on this question of confusion *as to names*. It consists only of predictions as to what the witnesses *feared might* occur *if* enrichment *were accompanied by abuses*. No abuses were shown. No foundations of fact were laid for these *conditional* predictions.[12] No consumer tests were taken; no proof of actual cases of confusion was made. Moreover, the predictions were only the statements of opinion by persons who made no claim of being expert upon the question. Some of the witnesses were eminently qualified in their fields as scientists, but none of them was qualified as a prophet.[13]

Accordingly the Circuit Court of Appeals was correct in holding (R. 686):

> "The findings and argument predicated upon the possibilities for confusion of consumers, in optional partial enrichment, carry little, if any, weight. There was no evidence in support of such possibilities and they are entirely speculative and conjectural."

[12] The opinion of an expert witness must be based on facts in evidence (32 C. J. S. 219).

[13] The Administrator says that respondent did not object to this testimony (Adm. Br. 27n). But he knows that the testimony was taken with respect to flour with which respondent was not particularly interested and that, accordingly, respondent was not present by counsel. He also knows that in these hearings qualification has not been generally considered as going to admissibility but rather as bearing on weight. The Administrator also says that respondent did not except to the findings on confusion (Adm. Br. 27n). In this he is mistaken (Exception I. R. 598. By typographical error, Finding 83 is there quoted as embracing 33 to 34 instead of 34 to 43). Moreover, Section 701 of the Act does not make exception a prerequisite to judicial review.

At a previous point in its opinion, the Court below said (R. 684):

> "The conclusion that the regulations will promote honesty and fair dealing comes closer, in our judgment, to being one of law than of fact. If so, we are not bound to accept it. On the other hand, if it be considered as a finding of fact, we are of the view that it is *without substantial support.*"

Fortification of foods is not new. Respondent has been adding Vitamin D to farina for ten years (R. 218). If there were any basis for the Administrator's findings, he could undoubtedly have proved the confusion and misleading of consumers upon the basis of respondent's practices. Furthermore, if any of respondent's competitors had faced dishonest competition during the past ten years, evidence thereof could readily have been produced. The record is entirely devoid of any evidence of the confusion and misleading of consumers or of dishonest competition. What the record does show is that, instead of the multitude of different kinds of farina which the Administrator purports to fear, only one other farina with vitamins has appeared (R. 562).

It has been pointed out by the Circuit Court of Appeals that the situation is similar to that in *Federal Trade Commission v. Raladam Company*, 283 U. S. 643, where this Court said (pp. 652-3):

> "• • • there is neither finding nor evidence from which the conclusion legitimately can be drawn that these advertisements substantially injured or tended thus to injure the business of any competitor or of competitors generally, whether legitimate or not. None of the supposed competitors appeared or was called upon to show what, if any, effect the misleading advertisements had, or were likely to have, upon his business. • • • It is impossible to say whether, as a result of Respondent's advertisements, any business was diverted, or was likely to be diverted, from others

engaged in like trade, or whether competitors, identified or unidentified, were injured in their business, or were likely to be injured, or, indeed, whether any other anti-obesity remedies were sold or offered for sale in competition, or were of such a character as naturally to come into any real competition with Respondent's preparation in the interstate market. *All this was left without proof and remains, at best, a matter of conjecture. Something more substantial than that is required as a basis for the exercise of the authority of the Commission.*"

The Administrator seeks to justify the substitution of guesswork and speculation for evidence upon the authority of *Electro Thermal Co.* v. *Federal Trade Commission*, 91 F. (2d) 477, 480. In that case, however, the abuses were *proved* and the court merely presumed the resultant injury from such *proved* abuses. The Administrator also cites *Federal Trade Commission* v. *Raladam Co.*, 316 U. S. 149, 151-152.[14] But in that case, too, the fact of deception was *proved* and this Court presumed the injury upon the basis of *proved* deception.[15] Upon the basis of these cases[16] the

[14] Another controversy between the same parties as were involved in *Federal Trade Commission* v. *Raladam Co.*, 283 U. S. 643, which is discussed above.

[15] This Court pointed out that in the prior *Raladam* case there was neither finding nor evidence from which the conclusion could be drawn and then went on to say: "This time the Commission found with meticulous particularity that Raladam had made many misleading and deceptive statements to further sales of Marmola; * * *"

[16] The Administrator also cites the trade-mark cases of *McLean* v. *Fleming*, 96 U. S. 245, 251, *United Drug Company* v. *Obear-Nester Glass Company*, 111 F. (2d) 997, 999-1000, and *Charles Broadway Rouss, Inc.* v. *Winchester Co.*, 300 F. 706, 723-724 (Adm. Br. 29n). But in these cases, too, the facts of the similarity between the parties' marks were *proved* and the presumption that confusion would be likely to result was based upon these *proved* facts. Compare *Kellogg Company* v. *National Biscuit Company*, 305 U. S. 111, 122, where this Court refused to indulge the presumption because the fact had not been proved. This Court said, "There is no evidence of passing off or deception on the part of the Kellogg Company; and it has taken every reasonable precaution to prevent confusion or the practice of deception in the sale of its product."

Administrator now asks this court, first to *presume* that abuses will occur and then to *presume* resultant injury from the *presumed* abuses. In the cited cases X was proved, and from X the court presumed Y. Now the Administrator claims the right to presume both X and Y where nothing has been proved. Of course, the Administrator must make a judgment *in futuro*. We only ask him to make his judgment *in futuro* on the basis of *proved facts*.

Predictions are not difficult to make, nor to obtain, if the prophet is not required to base his divinations upon facts or show that he is qualified to make his prophecies. If the obtaining of such predictions is the only requirement for the assertion of administrative control and is permitted to stand even though disputed by proved facts, it is difficult to imagine any situations over which such control cannot be exercised. Such a holding would emasculate the requirement that standards be based upon substantial evidence. The following admonition of the court in *National Labor Relations Board* v. *Sheboygan Chair Co.* (C. C. A. 7th), 125 F. (2d) 436, 439 is pertinent here:

> "The Board should not discard the positive credible testimony of witnesses in favor of an inference drawn from tenuous circumstances that at best could have supported only *an anemic suspicion*. Such an inference does not meet the test of substantial evidence."

In *Consolidated Edison Company* v. *National Labor Relations Board*, 305 U. S. 197, 230, this Court used these words:

> "* * * this assurance of a desirable flexibility in administrative procedure does not go so far as to justify orders without a basis in evidence having rational probative force. Mere uncorroborated hearsay or rumor does not constitute substantial evidence."

So also in *Appalachian Electric Power Company* v. *National Labor Relations Board*, 93 F. (2d) 985, 989, the court said:

> "• • • substantial evidence is evidence furnishing a substantial basis of fact from which the fact in issue can reasonably be inferred; and the test is not satisfied by evidence which merely creates a suspicion or which amounts to no more than a scintilla or which gives equal support to inconsistent inferences."

C.

Respondent's Contention that Vitamin D Should Be Included as an Optional Ingredient in the Farina Standard Is Supported by Substantial Evidence.

It has been pointed out that substantial evidence does not support the Administrator's treatment of Vitamin D whereby it was excluded from the farina standard and relegated to another standard for a hitherto unknown product which was given the name of "enriched farina." Not only was there not substantial evidence to support this treatment, there was in fact substantial evidence in opposition to it.

In addition to the proof of the long established usage by respondent of Vitamin D in its product (R. 218), the record shows that a deficiency of Vitamin D exists in large numbers of infants and children (R. 84);[17] that Vitamin D is valuable as an added nutrient in farina in the prevention and therapy of rickets and in the building of strong bones and teeth (R. 78), particularly in infants and children who make up a large class of farina consumers;[18] and that re-

[17] It has been pointed out that this widespread deficiency of Vitamin D in infants and children is specifically found by Administrator's Finding 35 (R. 617).

[18] Administrator's Finding 81 (R. 626).

spondent's product has received excellent consumer acceptance (R. 218). Respondent also adduced a mass of expert testimony to the effect that Vitamin D should be permitted as an optional ingredient in farina (R. 86, 217-8, 422-3, 433, 555-6).

It is to be noted that all of the evidence respecting vitamin and mineral additions to *farina* was on the basis of such addition as optional ingredients.[19] Indeed, there is nowhere in the record a scintilla of evidence concerning the non-existent product "enriched farina." The testimony introduced by the Administrator himself related not to "enriched farina," but only to farina.[20] Evidence offered by others also related only to farina alone and to farina with optional ingredients (R. 216-225, 266-322, 421-434, 555-556). The first notice to respondent that the hearing had given birth to a new product was the issuance of the Proposed Orders and Findings (R. 567).[21]

It is submitted that the above discussion demonstrates that the Administrator ignored the testimony adduced by the respondent and substituted therefor inadmissible predictions of his own witnesses, thereby nullifying the statutory requirement for substantial evidence.

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[19] Testimony of Doctor Scott (R. 76-93, 421-434), Doctor Gunderson (R. 216-225), and Doctor Harris (R. 266-322).

[20] Testimony of Joseph Calloway, Jr. (R. 205-213) and Dr. Virell E. Munsey (R. 213-216).

[21] The hearing had been entitled as follows: "In the Matter of a Definition and Standard of Identity for each of the following foods: • • • (I) Farina; and (J) Semolina" (R. 12). In the Proposed Order and Findings the caption had been changed to read: "In the Matter of a Definition and Standard of Identity for each of the Following Foods: • • • (M) Farina; (N) Enriched Farina; (O) Semolina" (R. 567).

III.

THE FARINA AND ENRICHED FARINA STANDARDS DO NOT ACCOMPLISH THE PURPOSES OF THE ACT.

A.

The Purposes of the Act Are to Secure the Purity of Foods and to Inform Purchasers of What They Are Buying.

Although from time to time the Administrator seems to argue that his regulatory powers are the same as those of Congress (*supra* pp. 33-4), it is beyond sound dispute that his powers are delegated and consist only of those plainly explicit in or reasonably to be inferred from the Act granting him the powers. To determine his powers, we must first know the purposes of the Act. In part, Section 401 of the Federal Food, Drug and Cosmetic Act of 1938 (21 U. S. C. A. 341) reads:

> "Whenever in the judgment of the Administrator *such action will promote honesty and fair dealing in the interest of consumers*, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, *a reasonable definition and standard of identity*, a reasonable standard of quality, and/or reasonable standards of fill of container: • • •"

In support of the farina standard and the enriched farina standard which the Administrator promulgated in furtherance of his dietary "food standards program" or "enrichment program,"[1] he argues that there is a tendency toward consumer confusion and that if the standards he has promulgated for farina and enriched farina minimize such confusion in enriched foods, public health will be benefited and honesty and fair dealing thus promoted.

[1] So called in the Administrator's Petition for the Writ of Certiori, pages 12 and 15.

Section 10, as amended, of the Food and Drug Act of 1906 (21 U. S. C. 10) contained a provision empowering the Secretary of Agriculture to promote certain standards for canned foods. That Section used language identical in its pertinent parts to the language in Section 401. It empowered the Secretary of Agriculture to promulgate reasonable standards of quality, etc., for certain canned foods there covered and he was limited in his power to promulgate such standards to those that would in his judgment "promote honesty and fair dealing in the interest of consumers." This Section was construed in *Nolan* v. *Morgan*, 69 F. (2d) 471, (C. C. A. 7). The court interpreted the words in the statute "promote honesty and fair dealing in the interest of consumers" as meaning what this Court in *U. S.* v. *Antikamnia Chemical Company*, 231 U. S. 654, 665, said the Food and Drug Act of 1906 as a whole meant, that is:

> "The purpose of the Act is to secure the purity of food and drugs, and to inform purchasers of what they are buying."

And again interpreting the words "promote honesty and fair dealing in the interest of consumers" the Seventh Circuit Court of Appeals in the present case said (R. 684-5):

> "That the promotion of honesty and fair dealing was intended by Congress to mean something other than the promotion of the consumers' health is plainly ascertainable from a study of the Act. Likewise, it is clear that action was not authorized merely to avoid confusion on the part of consumers, nor to educate the public as to dietary requirements. If Congress had so intended, it would, no doubt, have employed the appropriate language. While there may be some relevancy between the promotion of health and that of honesty and fair dealing, they certainly are not synonymous terms. Injury to health does not necessarily follow from dishonesty and unfair dealing in food products.

and neither does health improvement necessarily follow from honesty and fair dealing."

B.

The Farina and Enriched Farina Standards Do Not Secure the Purity of Foods Nor Do They Inform Purchasers of What They Are Buying.

Under the Federal Food, Drug and Cosmetic Act there are only two things which are actionable either by seizure and condemnation or by criminal proceedings. One is in case the food be *adulterated* and the other is if it be *misbranded*. Since the Administrator urges that standards of identity "might condemn wholesome nonconforming foods without benefit of reprieve by label disclosure" (Adm. Br. 43-4), he does not invoke Section 402 relating to adulterated foods. He admits that farina with Vitamin D added is a wholesome product and that there is no question of the use in or addition to that product of any harmful or deleterious substance. Consequently the Administrator's exclusion of Vitamin D as an optional ingredient in farina does not aid in securing the purity of foods. The standard, then, must be defended upon the basis of educating or informing the public. On the subject of informing consumers the Court below had this to say (R. 686-7):

> "Furthermore, we should think that a product manufactured in accordance with the regulations in suit *would tend to increase rather than retard confusion. This is especially true as to enriched farina.* No such product has been sold heretofore under that designation. The manufacturer will be required only to label it 'enriched farina' unless the option to add Vitamin D is exercised, in which case such addition must be stated. *How the ordinary consumer will be informed so as to avoid confusion as to what is meant by enriched farina, its contents, or the benefits to be expected from its use,*

> *is a mystery which we are not able to fathom.* How the contention that confusion is likely to result from a product, such as petitioner's, *which truthfully informs the consumer as to what he is buying*, can be reconciled with the contention that a product sold as enriched farina, without any further description, will lessen or avoid confusion, is beyond our comprehension."

The Administrator's argument that his standards will tend to lessen confusion all seems to hinge upon his fear, unsupported by evidence, of possible *advertising* abuses (Adm. Br. 24, 26-27). It has heretofore been shown that this so-called evidence does not constitute any basis for the Administrator's findings respecting confusion (*supra* pp. 40-46). However, the Federal Trade Commission under the Wheeler-Lea Amendment has jurisdiction over false and misleading advertising of foods, drugs and cosmetics.[2] It has the power and the duty to prohibit, enjoin and punish false or misleading advertising. As a matter of fact, the Vitamin B complex restoration program of the Administrator suggests "a tremendous advertising campaign" (R. 116) in which in every possible manner **Whole Wheat Values** or **Restored to Whole Wheat Values** would be stressed either without qualification, or with the obscure statement "restored to whole wheat values of Vitamin B_1, nicotinic acid and iron." No reference would be made to the absence of bran or reduction in amount of germ or any other change

[2] Federal Trade Commission Act, as amended, 15 U. S. C. A. 41. The House Committee in its report on the final draft of the Wheeler-Lea Amendment to the Federal Trade Commission Act filed August 19, 1937, as House Report 1613, 75th Congress, First Session, said:

> "The common motive of false advertisement is the same in every line of industry, to gain an economic advantage through defrauding or misleading the purchaser. This method of protecting the public should be harmonized and unified under one organization with consistent and uniform methods of enforcement and penalization."

in or damage to the nutritive values of the product caused by the processing, nor to the fact that the restored values are insignificant (*infra* p. 59).

Since respondent began marketing its product in April, 1932, the label has clearly and without ambiguity informed purchasers of what they are buying. It has described the product as "Quaker Farina Wheat Cereal enriched with Vitamin D." No expert testimony is needed to demonstrate that this description of the product is honest and is clearer, more specific, and less likely to confuse anyone than the mere description of the product as "enriched," which does not inform the purchaser in what respect the enrichment has been accomplished. The inferences which may be drawn from the blanket description "enriched" are unlimited. It could mean that powdered milk had been added. It could mean that the protein content had been stepped up. It could mean that the product was richer in fats or carbohydrates. Certainly such a standard does not inform consumers of what they are buying.

Moreover, the record shows that respondent's enrichment is no *partial* enrichment with Vitamin D. Respondent's product contains in a single serving *100 per cent* of the consumer's minimum daily requirements for this vitamin (R. 218). Contrast this with the Administrator's enriched farina standard which provides for the addition of varying quantities of Vitamin B_1, riboflavin, nicotinic acid and iron (*infra* p. 59), none of them to the extent of the consumer's total minimum daily requirements. In determining the amount of vitamins to be added, the Administrator has ignored the mass of testimony bearing upon the consumers' requirements and has based his enrichment standard upon the insignificant and utterly irrelevant requirement of the wheat berry (Adm. Br. 55). The Administrator's condemnation of "partial enrichment," therefore, would be more properly directed at his enriched farina

standard than at respondent's product. It is clear from the testimony of Dr. Elmer M. Nelson, Chief of the Vitamin Division of the Food and Drug Administration (*infra* pp. 57-9, R. 182) that the "indiscriminate enrichment" to which he took exception is not the substantial addition of any one vitamin or mineral, but the nutritively insignificant addition of *any one or more vitamins or minerals.*

C.

The Farina and Enriched Farina Standards Promote Dishonesty and Unfair Dealing.

The food, farina, has long been known and used. The food, enriched farina, was nonexistent until created by the Administrator. The record is clear (*supra* pp. 49-50) that the addition of Vitamin D to farina *improves* the product by making available to infants and children Vitamin D needed by them to combat the deficiency of Vitamin D which the Administrator has found exists in "large numbers of infants and children" (Finding 35, R. 617). Nevertheless, the Administrator would make it a criminal offense (Section 303 of the Federal Food, Drug and Cosmetic Act of 1938, 21 U. S. C. A. 333) for respondent to continue marketing its improved product "Quaker Farina Wheat Cereal enriched with Vitamin D." He would deprive consumers of an established, beneficial product which is admittedly superior nutritively to farina without Vitamin D added. He would deprive infants and children, who are the largest consumers of farina (R. 217, 272, 626), of Vitamin D which the Administrator has found they greatly need. And he says he would do this to promote honesty and fair dealing in the interest of consumers.

If there is any evidence in support of the Administrator's enriched farina standard it is evidence supporting a stand-

ard of "quality"[3] and not of "identity."[4] It requires no argument to demonstrate that farina is farina, whether or not additional vitamins have been added. The identity of the product is still the same. The quality of the product may be changed. If the enriched farina standard is a standard of quality and not a standard of identity, the farina standard of identity must, in the eyes of the Administrator himself, be wholly unreasonable because it does not contain provision even for the addition of the Vitamin B complex. But whether the enriched farina standard is a standard of quality (and thus void because no notice was given or public hearing held for a standard of quality as required by the Act) or a standard of identity, it constitutes a fraud upon the public. That this is so appears in part from the testimony of Dr. Elmer M. Nelson, Chief of the Vitamin Division of the Food and Drug Administration, the Administrator's main spokesman on vitamins at the hearings. He testified (R. 181-3):

> "Honesty and fair dealing in the interest of the consumer would not be promoted by including vitamins and minerals as optional ingredients of flour unless minimum standards are specified for each of the vitamins or minerals that may be used as optional ingredients.
>
> . . . . . .
>
> "Testimony has been offered at this hearing that the purpose of adding these optional ingredients which

[3] Webster's New International Dictionary, Second Edition, defines *quality* as: "1. That which constitutes (something); proper or essential being; character; nature; kind; 2. hence, an attribute; a characteristic; 3. Distinctive or peculiar character; distinctive trait, power, capacity, or virtue;"

[4] Webster defines *identity* as: "1. a Sameness of essential or generic character in different examples or instances; the limit approached by increasing similarity; as, the identity of the red in the rug with the red of a brick. b Sameness in all that constitutes the objective reality of a thing; . . ."

are intended to improve the nutrient value of bread is to benefit the public health. *Now, if flour which is fortified with vitamins or minerals is to serve that purpose, it becomes important that a substantial quantity of the vitamins or minerals should be added. I do not believe that the desired objective can be reached by restoration of flour as described by Dr. Wilder.*

"If we consider only the addition of calcium to white flour to the extent to make it equal in calcium content to whole wheat flour, we would then have roughly 10 per cent or less of the minimum daily requirement of calcium, and that is not accomplishing the purpose for which these vitamins and minerals should be added. *There should be some very definite improvement of the diet if such additions are to be of advantage to the consumer.*

"*Neither do I subscribe to the view expressed by Dr. Wilder that vitamins should be added to a type of food in which you expect to find that vitamin.* If people were actually guided in the manner that he suggested, they would choose whole wheat bread if their diet was insufficient in Vitamin B_1, rather than white bread, and we would have no necessity for fortification of white flour as has been here expressed.

"*I think there are other more important considerations in guiding us as to what vitamins should be added to flour.* Of prime importance is the question of whether flour is a suitable carrier so that the vitamin will not deteriorate, either in the flour itself or after it has been subjected to any cooking or baking process.

"Also of prime importance is whether the food which has been fortified with the vitamin and mineral actually reaches the group of people who should be benefited. *It has been testified here that dietary deficiencies are more likely to occur in low-income groups, and I concur in that opinion.* Therefore, the foods which will reach those groups should be fortified, if any foods are to be fortified with vitamins or minerals.

"If the addition of vitamins and minerals is to serve a useful purpose, it seems to me that if any vitamin is added to flour it should provide about one-fourth of the minimum daily requirement of that vitamin, and the same is true of minerals."

The following table clearly demonstrates that the Administrator's enriched farina standard obviously contravenes the principle of "definite improvement of the diet" in terms of minimum daily requirements as stated by Dr. Nelson:

Nutritional Substance	One serving enriched farina* Percentage of minimum daily requirement provided† Adult	Child	Infant
Required			
Vitamin B_1	10.37%	13.83% (6 to 12 yrs.) 20.74% (1 to 6 yrs.)	41.48%
Riboflavin	3.75%	Minimum Daily Requirement not declared	15.00%
Nicotinic Acid	Minimum Daily Requirement not declared		
Iron	3.75% (and for child 6 or more years)	5.00% (for child 1 to 6 yrs.)	Minimum Daily Requirement not declared
Optional			
Vitamin D	3.90%‡	3.90%	3.90%
Calcium	4.17%	4.17%	Minimum Daily Requirement not declared

*One ounce constitutes a serving (R. 86, 219).

†Based upon minimum daily requirements as provided in special dietary regulations, under Section 403 (j), (6 Fed. Reg. 5921-5926, issue of November 22, 1941). For quantities from which above percentages were determined, see Final Order (R. 637-8).

‡As contrasted with 3.90% provided by the enriched farina standard, respondent adds 100% of the minimum daily requirement of Vitamin D to one serving of its product (R. 218).

Thus the riboflavin, calcium, iron and Vitamin D provided for infants, children and adults, and the Vitamin B_1 provided for children and adults furnished by the Administrator's enriched farina standard are *insignificant* according to the testimony of Dr. Nelson, the Administrator's chief vitamin expert. Only in the case of the minimum daily infant requirements for Vitamin B_1 does the Administrator's enriched farina standard meet Dr. Nelson's principle of "definite improvement of the diet," that is, "approximately one-fourth of the minimum daily requirements."

The explanation of why the Administrator specified such *low* minimum amounts of the added ingredients (both required and optional) in "enriched farina" is apparent. He first established minimum quantities of these ingredients *per pound of enriched flour* (R. 629-30). He then provided *the identical amounts per pound for enriched farina.* His mistake was in ignoring—or simply completely *forgetting* —that the average daily serving of *flour* is *6½ ounces*, whereas the average daily serving of *farina* is *one ounce* (R. 47, 119, 183, 219). The result, of course, is that the average consumer of enriched *flour* will receive *six and one-half times* the amount of each of its vitamin and mineral additions as will the average consumer of enriched *farina.*

Unquestionably, Dr. Nelson, as Chief of the Vitamin Division of the Food and Drug Administration, has condemned such a product as the Administrator's "enriched farina" as "not accomplishing the purpose for which these vitamins and minerals should be added." And Dr. Wilder, upon whose testimony the Administrator obviously relies so much, agrees.[5] Nevertheless, the Administrator insists

[5]See his testimony, commencing R. 361, respecting minimum additions for 6½ ounces of *flour*, then considered the average daily consumption.

that if manufacturers meet this nutritionally insignificant standard they must, without qualification, label the product "enriched." The consumer is not told how the product is enriched, with what it is enriched, or how little it is enriched. The Administrator encourages unscrupulous manufacturers to mislead and defraud the consumer into believing he is getting a product of greatly superior nutritive value when in fact the improvement in the product is almost nonexistent.

Vitamin substances are expensive (R. 137). The above table shows that the addition of Vitamin B_1, riboflavin, nicotinic acid and iron as required ingredients before Vitamin D can be added will result in increasing the cost of farina to consumers without significant nutritional benefit. Instead of enriching its farina with insignificant quantities of a number of vitamins and minerals, respondent adds 100 per cent of the minimum daily requirements of Vitamin D to its farina, as contrasted with 3.90 per cent of the minimum daily requirements prescribed in the enriched farina standard. The Administrator's enriched farina standard obviously fosters "indiscriminate enrichment" of the worst kind. It does not "promote honesty and fair dealing." It does not "secure the purity of food and drugs, and inform purchasers of what they are buying." *U. S.* v. *Antikamnia Chemical Company*, 231 U. S. 654, 665.

Of course, the Administrator fixed the enriched farina standard with no intent to promote fraud. Obviously he fixed the standard for flour, and then extended it to farina without consideration of the different uses and functions of the two products. But that makes the standard no more reasonable. It is still illegal.

Clearly, the purpose of the Act will be served and consumers will be benefited by the inclusion of Vitamin D as

an optional ingredient in farina. There is no objection to naming it on the label, as respondent has always done.

IV.

THE ADMINISTRATOR CITES NO AUTHORITY JUSTIFYING HIS ORDER PREVENTING THE SALE OF FARINA IMPROVED BY THE ADDITION OF VITAMIN D.

That the present case is unlike any food or drug case which previously has come before the courts is perhaps best shown by the many authorities relied upon by the Administrator in his brief, particularly in the historical section dealing with the background and purposes of Section 401 of the Act (Adm. Br. 30-45). This is not a case in which an inferior product is being "palmed off on the public" or sold as "in imitation of" a superior product (Adm. Br. 38-40); the *Bred Spred* cases, *U. S.* v. *Fifteen cases of Bred Spred*, 35 Fed. (2d) 183; *U. S.* v. *Ten Cases More or Less Bred Spred*, 49 Fed. (2d) 87 and others, involving a product containing half the normal fruit content of jam being palmed off as and sold in imitation of jam). This is not a case involving the dilution of a product by increasing the content of a cheaper, inferior ingredient in the product and thereby lowering the content of the better, more expensive ingredient (Adm. Br. 47, 58; *Houston* v. *St. Louis Independent Packing Co.*, 249 U. S. 479, involving a product sold as sausage but containing more cereal, the cheap ingredient, and less meat, the expensive ingredient, than the product commonly known as "sausage"). This is not a case of selling an adulterated product which, as the Court below said, is "injurious to health and a fraud upon the public" (R. 688; Adm. Br. 57; *U. S.* v. *Carolene Products Co.*, 304 U. S. 144, involving the sale of skimmed milk compounded with fat or oil other than milk fat so as to *resemble* milk or cream; *Hebe* v. *Shaw*, 248 U. S. 297). This

is not a case of false labeling involving misrepresentation as to the source of origin of a product (Adm. Br. 47; *Huesner & Son* v. *Federal Trade Commission*, 106 Fed. (2d) 596, involving the use of the word "Havana" on cigars not made in Cuba). This is not a case of the addition of *poisonous* or *deleterious* substances to a product (Adm. Br. 37; Sections 402 (a), (1) and (2) of the Act). This is not a case of the substitution in a food of substances "which make the food appear *better* or of *greater value* than it is" (Adm. Br. 37). This is not a case in which "the public" has been "*victimized*" (Adm. Br. 43 n. 32; the Butter Standard Act, 21 U. S. C. A. 321a). This is not a case involving a food which is *substandard* in quality (Adm. Br. 12, 35). This is a case involving a product, farina with Vitamin D, which is *superstandard* in quality.

The Administrator's reliance throughout his brief on cases and fact situations such as outlined above and his inability to cite any case whatsoever even remotely resembling the case at bar, demonstrates quite conclusively, we think, that he has gone far afield in entering the order here under attack. The conclusion is inevitable that the Administrator in entering the order under review far exceeded his statutory authority, acted unreasonably, arbitrarily, capriciously and without substantial evidence.

CONCLUSION.

The right of parents to rear their children in health is fundamental. So is the right of a child to possess a body of sound skeletal structure. So is the right of one to make and honestly sell good food for human consumption. None of these rights should be limited beyond the minimum extent necessary in the public interest.

Congress did not, in Section 401 of the Food, Drug and Cosmetic Act of 1938, lodge power in the Administrator

to establish diets or create new foods. The Congressional grant does not go beyond that of promoting honesty and fair dealing in the interest of consumers by regulations promulgating for foods under their common names, as far as practicable, reasonable definitions and standards of identity, reasonable standards of quality and reasonable standards of fill of container. Farina with Vitamin D added has long been an established food. It is extensively used as a cereal food for children. Respondent's product contains enough Vitamin D to prevent the disease rickets. That it is a good food is not questioned. Its package label plainly identifies it. Its quality is unchallenged. Its quantity is truthfully represented.

The need for Vitamin D is great. This is particularly true among children. Farina is a good carrier. As such it has a ten year history. It is now a well-known product. That the consumers wish this food is proved by its wide use. That it is beneficial is not denied. It is wholly unreasonable to bar it. There is no need to bar it. So to do is contrary to the public interest. There is no substantial evidence warranting its death on the market. The evidence that it should endure is strong.

Under the excuse of preventing confusion, the Administrator offers manufacturers and the public a new food. It has never been made or sold. It is called "enriched farina." It will be more expensive to make. If produced, it is likely that it must be sold at a higher price. If made, the parents of children who can afford it may buy it. Those who cannot afford to buy it also will be economically unable to patronize the drugstore or the milkman. For them the only hope is exposure to sunshine. In the large centers and in most seasons of the year this is a false hope.

There is no confusion respecting the established food farina with Vitamin D added. There has been no confusion

for ten years. This does not warrant the postulate that there will be confusion in the future. "Enriched farina," if made and sold, will promote confusion. The manufacturer of "enriched farina", if one appears, needs only to label the product "enriched farina", unless Vitamin D is added or calcium is added, or wheat germ is added, or disodium phosphate is added. In each of these cases the additions must be stated. The phrase "enriched farina" is to mean that in the farina product is contained not less than 1.66 milligrams of Vitamin B_1, not less than 1.2 milligrams of riboflavin, not less than 6 milligrams of nicotinic acid or nicotinic acid amide, and not less than 6 milligrams of iron. This means that enriched farina will supply 20.74% of the minimum daily requirements of Vitamin B_1 for the child from one to six years of age and 5% of his minimum daily requirement of iron. In respect to optional ingredients, it may contain 3.90% of that child's minimum daily requirement of Vitamin D and 4.17% of his minimum daily requirement of calcium. As to infants, that is those a year old or less, some of these percentages are somewhat higher, but as to adults they are considerably lower. Since this is the import and the meaning of "enriched farina", the honest seller must either add to his label the explanation that the quantities of most of the added ingredients are insufficient to be of any value; or should make the quantities sufficient to be of value and meet somehow the competition of those who will be contented with the inadequate requirements of the Administrator's definition of "enriched farina".

The order of the Administrator is wholly unreasonable. It is not promotive of honesty and fair dealing. It is not in the interest of the consumer. It is unreasonable in respect to identity. It is unreasonable in respect to quality. The established food, farina with Vitamin D added, is in

wide use. The consumers have a right to use it. There is no confusion about it. The only confusion respecting farina is that which has been imported into the matter by the Administrator's order.

Respectfully submitted,

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SUPREME COURT OF THE UNITED STATES.

No. 424.—October Term, 1942.

Federal Security Administrator, Petitioner, *vs.* The Quaker Oats Company.	On Writ of Certiorari to the United States Circuit Court of Appeals for the Seventh Circuit.

[March 1, 1943.]

Mr. Chief Justice Stone delivered the opinion of the Court.

The Federal Security Administrator, acting under §§ 401 and 701(e), of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040, 1046, 1055, (21 U. S. C. §§ 341, 371), promulgated regulations establishing "standards of identity" for various milled wheat products, excluding vitamin D from the defined standard of "farina" and permitting it only in "enriched farina", which was required to contain vitamin B_1, riboflavin, nicotinic acid and iron. The question is whether the regulations are valid as applied to respondent. The answer turns upon (a) whether there is substantial evidence in support of the Administrator's finding that indiscriminate enrichment of farina with vitamin and mineral contents would tend to confuse and mislead consumers; (b) if so, whether, upon such a finding, the Administrator has statutory authority to adopt a standard of identity, which excludes a disclosed non-deleterious ingredient, in order to promote honesty and fair dealing in the interest of consumers; and (c) whether the Administrator's treatment, by the challenged regulations, of the use of vitamin D as an ingredient of a product sold as "farina" is within his statutory authority to prescribe "a reasonable definition and standard of identity."

Section 401 of the Act provides that "Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity . . . . In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose

of promoting honesty and fair dealing in the interest of consumers," designate the optional ingredients which shall be named on the label." By § 701(e) the Administrator, on his own initiative or upon application of any interested industry or a substantial part of it, is required to "hold a public hearing upon a proposal to issue, amend or repeal any regulation contemplated by" § 401. At the hearing "any interested person may be heard". The Administrator is required to promulgate by order any regulation he may issue, to "base his order only on substantial evidence of record at the hearing", and to "set forth as part of his order detailed findings of fact on which the order is based."[1]

Any food which "purports to be or is represented as a food for which a definition and standard of identity has been prescribed" pursuant to § 401 is declared by § 403(g) to be misbranded "unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients . . . present in such food". The shipment in interstate commerce of "misbranded" food is made a penal offense by §§ 301 and 303. "In a case of actual controversy as to the validity" of an order issuing regulations under § 401 any person "adversely affected" by it may secure its review on appeal to the Circuit Court of Appeals for the circuit of his residence or principal place of business. On such review the findings of the Administrator "as to the facts, if supported by substantial evidence, shall be conclusive." § 701(f)(1), (f)(3).

After due notice[2] and a hearing in which respondent participated, the Administrator by order promulgated regulations establishing definitions and standards of identity for sixteen milled wheat products, including "farina" and "enriched farina". Regulation 15.130 defined "farina" as a food prepared by grinding and bolting cleaned wheat, other than certain specified kinds, to a prescribed

[1] As enacted, the Act vested the foregoing powers in the Secretary of Agriculture. By §§ 12 and 13 of Reorganization Plan No. IV, 54 Stat. 1234, 1237, approved April 11, 1940, the Federal Food and Drug Administration and all functions of the Secretary of Agriculture relating thereto were transferred to the Federal Security Agency and the Federal Security Administrator.

[2] Respondent contended in the court below that the notice was inadequate. It appears to have abandoned that contention here, but in any event we think that it is without merit in view of respondent's participation in the original hearing, and in view of the publication of notice of a reconvened hearing devoted solely to the "propriety of the addition of vitamins and minerals to . . . (1) farina . . . ".

fineness with the bran coat and germ of the wheat berry removed to a prescribed extent. The regulation made no provision for the addition of any ingredients to "farina". Regulation 15.140 defined "enriched farina" as conforming to the regulation defining "farina", but with added prescribed minimum quantities of vitamin B_1, riboflavin,[3] nicotinic acid (or nicotinic acid amide) and iron. The regulation also provided that minimum quantities of vitamin D, calcium, wheat germ or disodium phosphate might be added as optional ingredients of "enriched farina", and required that ingredients so added be specified on the label. In support of the regulations the Administrator found that "unless a standard" for milled wheat products "is promulgated which limits the kinds and amounts of enrichment, the manufacturers' selection of the various nutritive elements and combinations of elements on the basis of economic and merchandising considerations is likely to lead to a great increase in the diversity, both qualitative and quantitative, in enriched flours offered to the public. Such diversity would tend to confuse and mislead consumers as to the relative value of the need for the several nutritional elements, and would impede rather than promote honesty and fair dealing in the interest of consumers."

On respondent's appeal from this order the Court of Appeals for the Seventh Circuit set it aside, 129 F. 2d 76, holding that the regulations did not conform to the statutory standards of reasonableness, that the Administrator's findings as to probable consumer confusion in the absence of the prescribed standards of identity were without support in the evidence and were "entirely speculative and conjectural", and that in any case such a finding would not justify the conclusion that the regulations would "promote honesty and fair dealing in the interest of consumers." We granted certiorari, 317 U. S. —, because of the importance of the questions involved to the administration of the Food, Drug and Cosmetic Act.

Respondent, The Quaker Oats Company, has for the past ten years manufactured and marketed a wheat product commonly used as a cereal food, consisting of farina as defined by the Administrator's regulation, but with vitamin D added. Respondent dis-

[3] The effective date of the riboflavin requirement has been postponed until April 20, 1943, because it appeared that the available supply was inadequate. 7 Fed. Reg. 3033.

tributes this product in packages labeled "Quaker Farina Wheat Cereal Enriched with Vitamin D", or "Quaker Farina Enriched by the Sunshine Vitamin". The packages also bear the label "Contents 400 U. S. P. units of Vitamin D per ounce, supplied by approximately the addition of 1/5 of 1 percent irradiated dry yeast".

Respondent asserts, and the Government agrees, that the Act as supplemented by the Administrator's standards will prevent the marketing of its product as "farina" since, by reason of the presence of vitamin D as an ingredient, it does not conform to the standard of identity prescribed for "farina", and that respondent cannot market its product as "enriched farina" unless it adds the prescribed minimum quantities of vitamin B_1, riboflavin, nicotinic acid and iron. Respondent challenges the validity of the regulations on the grounds sustained below and others so closely related to them as not to require separate consideration.

As appears from the evidence and the findings, the products of milled wheat are among the principal items of the American diet, particularly among low income groups.[4] Farina, which is a highly refined wheat product resembling flour but with larger particles, is used in macaroni, as a breakfast food, and extensively as a cereal food for children. It is in many cases the only cereal consumed by them during a period of their growth. Both farina and flour are manufactured by grinding the whole wheat and discarding its bran coat and germ. This process removes from the milled product that part of the wheat which is richest in vitamins and minerals, particularly vitamin B_1, riboflavin, nicotinic acid and iron, valuable food elements which are often lacking in the diet of low income groups. In their diet, especially in the case of children, there is also frequently a deficiency of calcium and vitamin D, which are elements not present in wheat in significant quantities. Vitamin D, whose chief dietary value is as an aid to the metabolism of calcium, is developed in the body by exposure to sunlight. It is derived principally from cod liver and other fish oils. Milk is the most satisfactory source of calcium in digestible form, and milk enriched by vitamin D is now on the market.

In recent years millers of wheat have placed on the market flours and farinas which have been enriched by the addition of various

[4] One witness at the hearing referred to estimates that over 95% of human consumption of wheat products is in the form of white flour.

vitamins and minerals. The composition of these enriched products varies widely.[5] There was testimony of weight before the Administrator, principally by expert nutritionists, that such products, because of the variety and combination of added ingredients, are widely variable in nutritional value; and that consumers generally lack knowledge of the relative value of such ingredients and combinations of them.

These witnesses also testified, as did representatives of consumer organizations which had made special studies of the problems of food standardization, that the number, variety and varying combinations of the added ingredients tend to confuse the large number of consumers who desire to purchase vitamin-enriched wheat food products but who lack the knowledge essential to discriminating purchase of them; that because of this lack of knowledge and discrimination they are subject to exploitation by the sale of foods described as "enriched" but of whose inferior or unsuitable quality they are not informed. Accordingly, a large number of witnesses recommended the adoption of definitions and standards for "enriched" wheat products which would ensure fairly complete satisfaction of dietary needs, and a somewhat lesser number recommended the disallowance, as optional ingredients in the standards for unenriched wheat products, of individual vitamins and minerals whose addition would suggest to consumers an adequacy for dietary needs not in fact supplied.

The court below characterized this evidence as speculative and conjectural, and held that because there was no evidence that respondent's product had in fact confused or misled anyone, the

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[5] The report of the officer presiding at the hearing enumerates the following varieties disclosed by the testimony:

"Flours, phosphated flours, and self rising flours—
1. One with added vitamin D;
2. One with added calcium;
3. One with added vitamin B_1, nicotinic acid, and calcium [produced by some 23 mills];
4. One with added vitamin B_1, calcium, and iron;
5. One containing wheat germ oil, said to furnish vitamin B_1, vitamin E and riboflavin;
6. One 'long extraction' flour containing vitamin B_1, riboflavin, calcium and iron."

"Farina—
7. One with added vitamin D;
8. One with added vitamin B_1, calcium and iron."

The labels used, and advertising claims made, for those products were not in the record. However, there was testimony that certain of them were sold under such names as "Sunfed", "Vitawhite", "Holwhite".

Administrator's finding as to consumer confusion was without substantial support in the evidence. It thought that, if anything, consumer confusion was more likely to be created, and the interest of consumers harmed, by the sale of farinas conforming to the standard for "enriched farina", whose labels were not required to disclose their ingredients, than by the sale of respondent's product under an accurate and informative label such as that respondent was using.

The Act does not contemplate that courts should thus substitute their own judgment for that of the Administrator. As passed by the House it appears to have provided for a judicial review in which the court could take additional evidence, weigh the evidence, and direct the Administrator "to take such further action as justice may require." H. R. Rep. No. 2139, 75th Cong., 3d Sess., pp. 11-12. But before enactment, the Conference Committee substituted for these provisions those which became § 701 (f) of the Act. While under that section the Administrator's regulations must be supported by findings based upon "substantial evidence" adduced at the hearing, the Administrator's findings as to the facts if based on substantial evidence are conclusive. In explaining these changes the chairman of the House conferees stated on the floor of the House that "there is no purpose that the court shall exercise the functions that belong to the executive or the legislative branches". 83 Cong. Rec., p. 9096. See also H. R. Rep. No. 2716, 75th Cong., 3d Sess., p. 25. Compare *Federal Radio Comm'n* v. *General Electric Co.*, 281 U. S. 464.

The review provisions were patterned after those by which Congress has provided for the review of "quasi-judicial" orders of the Federal Trade Commission and other agencies, which we have many times had occasion to construe.[6] Under such provisions we have repeatedly emphasized the scope that must be allowed to the discretion and informed judgment of an expert administrative body. *Federal Trade Comm'n* v. *Education Society*, 302 U. S. 112, 117; *Gray* v. *Powell*, 314 U. S. 402, 412; *Labor Board* v. *Link Belt Co.*,

[6] The provision adopted by the Conference Committee is one which was proposed as an amendment from the floor of the House by Mr. Mapes, a minority member of the House Committee and one of the House conferees. In proposing it he said that it was "the same as the court review section in the Federal Trade Commission Act with only such changes as are necessary to adapt it to the pending bill", and he referred to "similar" provisions in the Bituminous Coal Commission Act, National Labor Relations Act, Securities Exchange Act, and Federal Communications Act. 83 Cong. Rec., 7892, 7777-8.

311 U. S. 584, 597; *see Federal Communications Commission* v. *Pottsville Broadcasting Co.*, 309 U. S. 134, 141, 144. These considerations are especially appropriate where the review is of regulations of general application adopted by an administrative agency under its rule-making power in carrying out the policy of a statute with whose enforcement it is charged. Compare *Houston* v. *St. Louis Independent Packing Co.*, 249 U. S. 479, 487; *Opp Cotton Mills* v. *Administrator*, 312 U. S. 126, 156. Section 401 calls for the exercise of the "judgment of the Administrator". That judgment, if based on substantial evidence of record, and if within statutory and constitutional limitations, is controlling even though the reviewing court might on the same record have arrived at a different conclusion.

None of the testimony which we have detailed can be said to be speculative or conjectural unless it be the conclusion of numerous witnesses, adopted by the Administrator, that the labeling and marketing of vitamin-enriched foods, not conforming to any standards of identity, tend to confuse and mislead consumers. The exercise of the administrative rule-making power necessarily looks to the future. The statute requires the Administrator to adopt standards of identity which in his judgment "will" promote honesty and fair dealing in the interest of consumers. Acting within his statutory authority he is required to establish standards which will guard against the probable future effects of present trends. Taking into account the evidence of public demand for vitamin-enriched foods, their increasing sale, their variable vitamin composition and dietary value, and the general lack of consumer knowledge of such values, there was sufficient evidence of "rational probative force" (*see Consolidated Edison Co.* v. *National Labor Relations Board*, 305 U. S. 197, 229, 230), to support the Administrator's judgment that, in the absence of appropriate standards of identity, consumer confusion would ensue. *Federal Trade Commission* v. *Raladam Co.*, 283 U. S. 643, 651; *Federal Trade Commission* v. *Raladam Co.*, 316 U. S. 149, 151, 152; *Pacific States Box Co.* v. *White*, 296 U. S. 176, 181. Compare *McLean* v. *Fleming*, 96 U. S. 245, 251, 253-4, 255.

Respondent insists, as the court below held, that the consumer confusion found by the Administrator affords no basis for his conclusion that the standards of identity adopted by the Administrator will promote honesty and fair dealing. But this is tanta-

mount to saying, despite the Administrator's findings to the contrary, either that in the circumstances of this case there could be no such consumer confusion or that the confusion could not be deemed to facilitate unfair dealing contrary to the interest of consumers. For reasons already indicated we think that the evidence of the desire of consumers to purchase vitamin-enriched foods, their general ignorance of the composition and value of the vitamin content of those foods, and their consequent inability to guard against the purchase of products of inferior or unsuitable vitamin content, sufficiently supports the Administrator's conclusions.

We have recognized that purchasers under such conditions are peculiarly susceptible to dishonest and unfair marketing practices. In *United States* v. *Carolene Products Co.*, 304 U. S. 144, 149, 150, we upheld the constitutionality of a statute prohibiting the sale of "filled milk"—a condensed milk product from which the vitamin content had been extracted—although honestly labeled and not in itself deleterious. Decision was rested on the ground that Congress could reasonably conclude that the use of the product as a milk substitute deprives consumers of vitamins requisite for health and "facilitates fraud on the public" by "making fraudulent distribution easy and protection of the consumer difficult."

Both the text and legislative history of the present statute plainly show that its purpose was not confined to a requirement of truthful and informative labeling. False and misleading labeling had been prohibited by the Pure Food and Drug Act of 1906. But it was found that such a prohibition was inadequate to protect the consumer from "economic adulteration", by which less expensive ingredients were substituted, or the proportion of more expensive ingredients diminished, so as to make the product, although not in itself deleterious, inferior to that which the consumer expected to receive when purchasing a product with the name under which it was sold. Sen. Rep. No. 493, 73d Cong., 2d Sess., p. 10; Sen. Rep. No. 361, 74th Cong., 1st Sess., p. 10. The remedy chosen was not a requirement of informative labeling. Rather it was the purpose to authorize the Administrator to promulgate definitions and standards of identity "under which the integrity of food products can be effectively maintained" (H. R. Rep. 2139, 75th Cong., 3d Sess., p. 2; H. R. Rep. 2755, 74th Cong., 2d Sess., p. 4), and to require informative labeling only where no such standard had been promulgated, where the food did not purport to comply with a stand-

ard, or where the regulations permitted optional ingredients and required their mention on the label. §§ 403(g), 403(i); see Sen. Rep. No. 361, 74th Cong., 1st Sess., p. 12; Sen. Rep. No. 493, 73d Cong., 2d Sess., pp. 11-12.

The provisions for standards of identity thus reflect a recognition by Congress of the inability of consumers in some cases to determine, solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other.[7] We cannot say that such a standard of identity, designed to eliminate a source of confusion to purchasers—which otherwise would be likely to facilitate unfair dealing and make protection of the consumer difficult—will not "promote honesty and fair dealing" within the meaning of the statute.

Respondent's final and most vigorous attack on the regulations is that they fail to establish reasonable definitions and standards of identity, as § 401 requires, in that they prohibit the marketing, under the name "farina", of a wholesome and honestly labeled product consisting of farina with vitamin D added, and that they prevent the addition of vitamin D to products marketed as "enriched farina" unless accompanied by the other prescribed vitamin ingredients which do not co-act with or have any dietary relationship to vitamin D. Stated in another form, the argument is that it is unreasonable to prohibit the addition of farina to vitamin D as an optional ingredient while permitting its addition as an optional ingredient to enriched farina, to the detriment of respondent's business.

The standards of reasonableness to which the Administrator's action must conform are to be found in the terms of the Act construed and applied in the light of its purpose. Its declared purpose is the administrative promulgation of standards of both iden-

[7] A Message of the President, dated March 22, 1935, urging passage of the bill and particularly of the standard of identity provision, pointed out that "The various qualities of goods require a kind of discrimination which is not at the command of consumers. They are likely to confuse outward appearances with inward integrity. In such a situation as has grown up through our rising level of living and our multiplication of goods, consumers are prevented from choosing intelligently and producers are handicapped in any attempt to maintain higher standards." H. R. Rep. No. 2755, 74th Cong., 2d Sess., pp. 1-2.

The Chairman of the Food and Drug Administration testified before the Senate Committee that the provision for standards of identity which would reflect "the expectation of the buyer" was "one of the most important provisions of the Act." Hearings before a Subcommittee of the Senate Committee on Commerce on S. 1944, Dec. 7 and 8, 1933, pp. 35, 36.

tity and quality in the interest of consumers. Those standards are to be prescribed and applied, so far as is practicable, to food under its common or usual name, and the regulations adopted after a hearing must have the support of substantial evidence. We must reject at the outset the argument earnestly pressed upon us that the statute does not contemplate a regulation excluding a wholesome and beneficial ingredient from the definition and standard of identity of a food. The statutory purpose to fix a definition of identity of an article of food sold under its common or usual name would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition. As we have seen, the legislative history of the statute manifests the purpose of Congress to substitute, for informative labeling, standards of identity of a food, sold under a common or usual name, so as to give to consumers who purchase it under that name assurance that they will get what they may reasonably expect to receive. In many instances, like the present, that purpose could be achieved only if the definition of identity specified the number, names and proportions of ingredients, however wholesome other combinations might be. The statute accomplished that purpose by authorizing the Administrator to adopt a definition of identity by prescribing some ingredients, including some which are optional, and excluding others, and by requiring the designation on the label of the optional ingredients permitted.[8]

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[8] The standard of identity provision was repeatedly stated in the Committee reports to have been patterned on the Butter Standards Act of 1923, 42 Stat. 1500. Sen. Rep. No. 361, 74th Cong., 1st Sess., p. 10; Sen. Rep. No. 646, 74th Cong., 1st Sess., p. 4; Sen. Rep. No. 493, 73d Cong., 2nd Sess., p. 10; H. R. Rep. No. 2139, 75th Cong., 3rd Sess., p. 5. That Act was entitled "An Act to define butter and provide a standard therefor", and established a legislative definition and standard for butter. The Chairman of the House Committee which reported it said "The only things you can put into [butter] are salt, casein, the butter fat, and water. That is what the definition provides." Hearings, House Committee on Agriculture on H. R. 12053; 67th Cong., 2nd Sess., p. 25; see also H. R. Rep. No. 1141, 67th Cong., 2nd Sess., p. 4.

Also referred to as models for the standards to be promulgated under the present act were the advisory standards then being promulgated by the Pure Food and Drug Administration under the authority given by the Appropriation Act of June 3, 1902, 32 Stat. 286, 296, and subsequent acts. Hearing before a Subcommittee of the Senate Committee on Commerce on S. 1944, Dec. 7 and 8, 1933, p. 36. (Statement of Walter B. Campbell, Chief of Food and Drug Administration; Dept. of Agriculture.) The announcements promulgating these standards stated that they were "so framed as to exclude substances not mentioned in the definition." E. g., Dept. of Agriculture, Food and Drug Administration, Service and Regulatory Announcement No. 2, Revision 4 (1933) p. 1; *id.*, Rev. 8 (1936) p. 1.

Since the definition of identity of a vitamin-treated food, marketed under its common or usual name, involves the inclusion of some vitamin ingredients and the exclusion of others, the Administrator necessarily has a large range of choice in determining what may be included and what excluded. It is not necessarily a valid objection to his choice that another could reasonably have been made. The judicial is not to be substituted for the legislative judgment. It is enough that the Administrator has acted within the statutory bounds of his authority, and that his choice among possible alternative standards adapted to the statutory end is one which a rational person could have made. *Houston v. St. Louis Independent Packing Co.*, *supra*, 487.

The evidence discloses that it is well known that the milling process for producing flours and farinas removes from the wheat a substantial part of its health-giving vitamin contents, which are concededly essential to the maintenance of health, and that many consumers desire to purchase wheat products which have been enriched by the restoration of some of the original vitamin content of the wheat. In fixing definitions and standards of identity in conformity with the statutory purpose the Administrator was thus confronted with two related problems. One was the choice of a standard which would appropriately identify unenriched wheat products which had long been on the market. The other was the selection of a standard for enriched wheat products which would both assure to consumers of vitamin-enriched products some of the benefits to health which they sought, and protect them from exploitation through the marketing of vitamin-enriched foods of whose dietary value they were ignorant. In finding the solution the Administrator could take into account the facts that whole wheat is a natural and common source of the valuable dietary ingredients which he prescribed for enriched farina; that wheat is not a source of vitamin D; that milk, a common article of diet, is a satisfactory source of an assimilable form of calcium; that the principal function of vitamin D is to aid in the metabolism of calcium; and that milk enriched with vitamin D was already on the market.

We cannot say that the Administrator made an unreasonable choice of standards when he adopted one which defined the familiar farina of commerce without permitting addition of vitamin enrichment, and at the same time prescribed for "enriched farina"

the restoration of those vitamins which had been removed from the whole wheat by milling, and allowed the optional addition of vitamin D, commonly found in milk but not present in wheat. Consumers who buy farina will have no reason to believe that it is enriched. Those who buy enriched farina are assured of receiving a wheat product containing those vitamins naturally present in wheat, and, if so stated on the label, an additional vitamin D, not found in wheat.

Respondent speaks of the high cost of vitamin B_1 ($700 per pound), but there was evidence that the cost of adding to flour the minute quantities of the four ingredients required for enriched farina would be about 75 cents per barrel, and respondent concedes that the cost to it may be but a fraction of a cent per pound. The record is otherwise silent as to the probable effect of the increased cost on the marketing of respondent's product. On this record it does not appear that the increased cost has any substantial bearing on the reasonableness of the regulation.

We conclude that the Administrator did not depart from statutory requirements in choosing these standards of identity for the purpose of promoting fair dealing in the interest of consumers, that the standards which he selected are adapted to that end, and that they are adequately supported by findings and evidence.

Reversed.

Mr. Justice MURPHY and Mr. Justice RUTLEDGE took no part in the consideration or decision of this case.

Mr. Justice ROBERTS is of opinion that the judgment should be affirmed for the reasons stated by the Circuit Court of Appeals, 129 F. 2d 76.

A true copy.

Test:

Clerk, Supreme Court, U. S.